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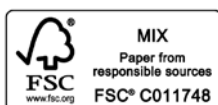
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The Use of Economic and Business Expertise in International Arbitration

Charles River Associates

Andrew Tepperman



Introduction

Parties to commercial contracts involved in international arbitration proceedings are eventually faced with the question of what types of expert witnesses to retain. A common approach has been to retain legal experts to address questions of liability (for example, contract interpretation), and accounting experts to address quantum (i.e., damages). While this tactic has the virtue of simplicity and prevents any potential overlap in expert opinions, it may also foreclose a party's opportunities to develop valuable additional support for its liability and/or damages claims. For this reason, in complex disputes involving higher stakes, we have recently seen disputants in international arbitration proceedings make effective use of economic and business expertise that encompasses a range of issues, broader than the typical quantum expert's mandate.

Several advantages may accrue to a party retaining such an expert. First, and most fundamentally, the expert will be able to provide industry context for the dispute, from a liability and damages perspective, and serve as a resource to educate arbitrators who might not be familiar with relevant aspects of the marketplace at issue. Second, the expert's testimony may assist the arbitrators through support with reference to academic literature and/or commonly understood industry practices. The expert may also be able to comment on the quality and reliability of data provided during the proceedings, from a business and/or statistical perspective. Third, retaining an expert on economic and business issues can provide a party with an important competitive advantage in the event the opposing party has not engaged a comparable expert. Should this be the case, the opposing party may be unable to execute a well-informed cross-examination and put forth compelling expert testimony in response.

In this article, I discuss a set of specific liability and damages issues that could be addressed by economic and business expert testimony. The context is assumed to be an international arbitration proceeding involving firms in the pharmaceutical industry in which the key issue in dispute is an alleged breach of contract pursuant to an obligation to exercise commercially reasonable efforts. In our experience, disputes involving commercially reasonable efforts issues are increasingly common, and provide a rich set of possibilities for expert testimony. In the pharmaceutical industry, two common types of contractual agreements involving commercially reasonable efforts are contracts to develop and commercialise a product, and contracts to promote a product that has already been launched. In our experience, qualitatively similar expertise can be deployed across a range of industries and contractual situations.

Liability Issues

There are a variety of ways in which economic and business expertise can assist a party with the liability side of a commercially reasonable efforts case. Purely legal issues regarding contract interpretation are assumed to be outside the proposed mandate. This section considers three potential contributions an economic and business expert can make to liability arguments. First, the expert can assist in identifying indicators of performance, relevant data within the context of the industry that could be used to measure the extent to which the allegedly breaching party complied with its contractual obligations. Second, having identified such data, the expert can assist in the assessment of commercial factors that might be expected to have a bearing on the magnitude of effort that would be consistent with performance under the contract. Third, the expert can engage in rigorous analysis of the strengths and weaknesses of the available data.

Indicators of Performance

Contracts requiring a partner to exercise commercially reasonable efforts typically do not specify in great detail the complete range of activities to be undertaken by the partner together with the required levels of those activities. This is for good reason, as in many business relationships it is impractical to attempt to foresee all possible relevant eventualities and define the steps to be taken. Commercially reasonable efforts provisions are thus intended to be a low-cost, contractually-efficient mechanism ensuring that the party undertaking the obligation takes appropriate actions given the circumstances at the time. From a business perspective, commercially reasonable efforts provisions can be understood as implying a set of relative obligations. The party's efforts are expected to be in line with what similarly situated businesses would normally do, relative to the commercial gains that could be expected from successful efforts. The expert's business expertise and experience would inform these assessments.

In many cases, measures of effort along particular dimensions may be observed directly. For example, in a drug development and commercialisation agreement, a party's expenditures on clinical trials (and the timing of those expenditures) can be observed, as can expenditures on activities relating to regulatory filing and launch preparation. Likewise, in an agreement to promote a drug, there is typically a range of direct indicators of effort, such as the number of visits made by sales representatives to doctors to promote the drug

by explaining its approved uses and clinical attributes (commonly referred to as “details”), the prominence a particular drug receives during those visits, the number of sponsored conferences, etc.

However, for the purposes of assessing whether a party complied with a commercially reasonable efforts obligation, it may not be sufficient to only refer to these input measures. What may appear to be a substantial level of activity may not comply with a commercially reasonable efforts obligation if those activities are not properly directed or if they are mis-timed relative to critical market developments. In other words, an apparently large effort may prove to be insufficient when examining its consequences. Alternatively, what may appear to be a small level of effort may well be commercially reasonable if the effects of those efforts in the marketplace are consistent with what comparable businesses would expect in similar circumstances.

Accordingly, it is frequently important to refer to a range of indicators that may indirectly reflect the extent to which a commercially reasonable efforts obligation has been satisfied. These indicators, some of which are discussed below, are indirect because they consider the outcomes of those efforts. The parties to the contract are generally aware of many of these indicators, and they may be referred to in documents produced in the case (such as correspondence between the parties, steering committee memoranda, etc.). However, expert testimony from an economic and business perspective can be useful in narrowing the focus to a specific set of indicators, in part by disentangling which among a range of indicators demonstrate a commitment of commercially reasonable efforts, and which could be ascribed to other causes relating to external business or economic circumstances.

For example, consider the hypothetical development and commercialisation contract referred to above. The party responsible for developing and launching the product is assumed to have made certain expenditures relating to clinical trials, the securing of regulatory approval, and launch preparation. A more nuanced understanding of the extent to which these expenditures were consistent with commercially reasonable efforts may be gained by considering how expenditures were allocated to the development of various drug indications (approved uses) for which approval might be sought in light of the market opportunity and likelihood of clinical success. Commercially reasonable efforts may entail pursuit of just some of the possible range of approved uses, rather than all.

Components of the commercialisation plan provide another set of indicators. This is a potentially rich source of insight into the efforts made by the party responsible for developing and launching the product, allowing evaluation in several dimensions, potentially including: the adequacy of qualitative and quantitative market research that has been carried out; recommendations for pricing and access for the drug, in terms of the extent of its reimbursement by payers such as insurance providers; and the comprehensiveness of the marketing and promotion strategy for the product in light of industry norms (covering, for example, expected detailing and other forms of advertising, and training efforts and compensation schemes for the sales force). An expert may assess whether the results of the efforts made are indicative of commercially reasonable efforts.

Consider the second example, in which the party is responsible for promoting an already-launched drug (either as the sole promoter or co-promoter). As noted above, there is typically considerable information on the promotional inputs, including the number of internally recorded details, meetings, conferences, and so on. Expertise in business and economic issues can help identify indicators that may better capture the presence or absence of commercially reasonable efforts. For example, a properly executed promotional strategy should result in a share of voice (based on

sales representative meetings with doctors) that could lead to prescribing the drug. Share of voice places the detailing effort in the context of other competitors in the marketplace who would be presumed to be executing commercially reasonable efforts on behalf of their products. Other metrics that may prove useful in evaluating promotional performance might include: survey results on the extent to which the approved message was delivered; measures of intent to prescribe as reported by doctors in surveys; and the prominence accorded to the drug within the set of other drugs promoted by the company’s sales force. Again, the relevance and probity of data along each of these dimensions is within the purview of an economic and business expert in the industry. It is also worth noting that all of these indicators are commonly tracked by those involved in the business at issue in the ordinary course of their activities; the expert’s role is largely putting the data into context and evaluating it, rather than creating new indicators from scratch.

Relevant Commercial Factors

The commercially reasonable efforts standard is generally not met by performing a set number or amount of a particular set of activities. While commercial contracts may define specific performance metrics, these are often considered to be minimums for performance rather than targets to be just met. What is commercially reasonable, however, should depend on relevant market circumstances. After all, it is the variability and variety of market circumstances that led the parties to incorporate a commercially reasonable efforts obligation in the first place.

With this in mind, when assessing contractual performance under a commercially reasonable efforts obligation, it is important to identify those factors that have a bearing on the appropriate level of efforts, and to understand how efforts are conditioned by these factors. Frequently, the contractual definition of commercially reasonable efforts includes a list of the factors to be taken into account. Whether explicitly set out in this fashion or not, factors of key importance include the potential of the product and the competitiveness of the marketplace. As might be expected, efforts are likely to be different for a large and rapidly growing marketplace that is highly competitive than for one that is small and served by few sellers. For any pharmaceutical product, therefore, it is recognised that efforts would need to adjust appropriately as the magnitude of the opportunity is revealed and the lifecycle of the product progresses. As noted above, from a business perspective, the standard requires efforts to be large enough that they are consistent with standard business practices in the circumstances, but not too large in light of the perceived profit opportunity available.

Expert testimony can elucidate the connections between efforts and the various factors that may be taken into account. Take the building of awareness among physicians, one of the fundamental goals of pharmaceutical marketing. In a development and commercialisation agreement, the efforts in terms of building awareness strongly depend on the extent of competition in the marketplace. For a first-in-class product, much of the work is focused on generating awareness of the disease and the impending launch. For a product in a class with many competitors, the awareness effort will focus on differentiating the product from other drugs already available. What about the magnitude of the efforts to be deployed? Here, a realistic assessment of the market opportunity potentially available to the product, and the probability of accessing that opportunity, is paramount. Products expected to have greater market potential tend to receive more launch planning activities and with greater intensity. Tactics that may be used to support the launch of a potential blockbuster product to be prescribed by a variety of doctors with

different specialties may not be used to support the launch of a niche product to be prescribed by specialists. Expertise honed in assisting pharmaceutical companies with launch planning, as provided by an economic or business expert, will help the arbitral tribunal understand what constitutes commercially reasonable efforts in the context of a product's commercial potential.

Similar considerations apply in evaluating an agreement to provide promotional efforts. Again, the appropriate effort level should be attuned to the product opportunity, the stage in the lifecycle, and the competitiveness of the marketplace. In a large and growing market, other things being equal, it may be commercially reasonable to deploy a larger promotional effort to better exploit the opportunity. A product at an earlier stage in its lifecycle will require more substantial promotional efforts to generate awareness and secure trial than a more established product. And with more competing products, it may be desirable to pursue a higher share of voice in order to generate awareness, secure trial, and build share for the product.

Given that the commercially reasonable efforts standard is a relative one, these considerations need not be evaluated in the abstract. Data regarding efforts put forth on behalf of other products or analogs may provide indicators of commercially reasonable efforts, after adjusting for market potential, stage of lifecycle, and competitiveness of the marketplace.

Data Questions

Evaluating the adequacy of efforts may involve reference to data collected by third party data providers. For example, one or both of the parties to a contract may regularly obtain survey data on measures of the quality and/or quantity of the promotional effort, including the memorability of promotional visits, the messaging content of those visits, and the resulting level of intention to prescribe or use the product. A party to an arbitration proceeding may seek to question the reliability of the data, for example in terms of the survey mechanism used to collect the data and the sample sizes of the data once collected, and on which inference is based. In most cases, these issues do not come up, and the parties can reach agreement as to the merits of various data sources. But in those instances in which data use is in dispute, an expert familiar with the use of the same or similar data can be valuable to the party attempting to use the data to support its claim.

First, to the extent that use of the data is standard in the industry and the data are typically relied on to make business decisions, then this will tend to be evidence in favour of the reliability of the data or of certain analyses using the data. A foundation of reliability will be further supported by evidence that companies purchase the data at substantial cost to support their ordinary business operations (i.e., not just for use in adjudicating disputes), consistent with their anticipated value. An expert on economic and business issues can speak to the extent of use of the data in the industry (including the circumstances in which certain data are known to be particularly effective or limited). Second, an expert may be able to address issues of statistical reliability. Due to basic statistical principles, a survey that is properly designed and conducted will yield estimates that are sufficiently accurate to justify support for commercial endeavors. Standard statistical principles inform the assessment of data. Accordingly, an attempted critique of the use of the data may be evaluated using standard statistical principles and, if the critique lacks merit, can be effectively dismissed.

Damages Issues

Damages issues will arise, should the arbitral tribunal find a breach has occurred due to a failure to provide commercially reasonable efforts. A reliable damages analysis will articulate how commercially reasonable efforts would differ from what was actually done, and how that difference, as opposed to other changes in the marketplace, would impact sales of the product and thereby generate damages. The hypothetical "but-for" world created for damages purposes should be consistent with the theory of liability; the connection between effort level, sales, costs, and ultimately damages can be elucidated by expert testimony.

The Connection Between Performance and Damages

The damages inquiry starts by considering how the allegedly inadequate efforts would have translated to a different outcome in the marketplace had they met the commercially reasonable benchmark. In many cases, expert judgment can assist in exploring how, if at all, a change in efforts would have led to a different market outcome. To do this, the mechanism that links efforts, revenues, and costs will typically need to be explicitly characterised. This can involve a certain amount of economic modelling, depending on the complexity of the underlying factors that affect demand for the product.

Consider first a relatively simple case involving the development and commercialisation agreement. It may be alleged that failure to exert commercially reasonable efforts led to a decision to not pursue development of certain indications for the drug in question, with the result that the marketing of the drug for these indications is (allegedly) substantially delayed. For this claim to be a plausible source of damages, commercially reasonable efforts must imply an obligation to pursue regulatory approval for these indications. Otherwise, it would not be apparent that any alleged delay in the launch of these indications would generate damages. Additionally, should this condition be satisfied, the damages model must provide a quantitative link between the lack of commercially reasonable efforts and the alleged delay in approval. Expert testimony may illuminate whether this is even feasible and, if so, under what timeline. A plausible damages claim would have to set out the likelihood and timing of approval and the associated costs. For example, for an early stage product that has not commenced the required clinical trials, a damages estimate based on the alleged launch delay may be too speculative.

Alternatively, consider an agreement to promote a drug. In this case, the mechanism linking efforts to sales and costs might be modelled as deriving from detailing or share of voice for the product. The key empirical relationship here is related to the standard concept in pharmaceutical marketing (and the marketing of most other products) that the level of promotional effort (via share of voice) influences the market share that a seller can capture. It is also generally understood that accumulated experience with the products on the market has a bearing on the influence of share of voice. Other things being equal, the longer a product has been effectively promoted on the market, the less significant is current promotion relative to the cumulative experience that purchasers have had, taking into account past exposure to the product's promotional message. The relationship between share of voice and share of market can be determined based on actual market data, and supported by reference to the relevant academic and professional

literature. Based on this data, a representation can be constructed of the effects that the accumulated stock of past detailing effort and the flow of current detailing effort would have on share of market. The modelling here does not have to incorporate the full analytical complexity that appears in the published academic literature. It is sufficient for the model to capture the effects driving sales, i.e., past and current promotional efforts, in an analytically tractable manner. It is then a matter of determining how share of voice would have differed had commercially reasonable efforts been pursued, what would have been the costs of that additional effort, and how (and when), based on these estimated relationships, share of market would have reacted.

Duration of the Damages Period

Closely related to the set of relationships connecting the provision of efforts with revenues and costs is the issue of the duration of the damages period. It may seem natural to assume the damages period should be equivalent to the period in which the contract would have been in force. This is not necessarily the case. Consider the agreement to provide promotional efforts. If a product's promotion were to cease, one would not expect that product's sales to collapse immediately. The reason is that as noted above, purchasing behaviour associated with the product has accumulated due to past promotional activity and purchasers' history of using the product. Over time, as purchasers try other products and the messaging associated with the brand fades in the memory of purchasers, the product's share would be expected to decay correspondingly. Analogously, the additional contribution to share of voice that would be contributed by a contractual partner providing commercially reasonable efforts can be expected to result in a stock of promotional goodwill that has a continuing impact on share of market, even once the full term of the agreement expires. Therefore, damages resulting from the failure to provide these efforts may extend beyond the term of the contract.

To the extent that any benefits would persist as a result of commercially reasonable efforts, it is appropriate to account for these benefits in computing damages. If there is a failure to provide effective promotional efforts, for example, then an estimate of damages must include the expected impact on the period after which the agreement otherwise would have expired. Identifying the effect of commercially reasonable efforts on the duration of damages requires a model that describes, to a sufficient degree of accuracy, the relationship between efforts, revenues, and costs. Once this relationship is adequately accounted for, it is possible to estimate the full period during which cash flows in the hypothetical "but for" circumstance exceed those actually expected. Conceivably, however, external circumstances may dictate when damages can be reasonably expected to end. For example, entry of a new generation of products or by generic versions of the drug may be expected to occur at a reasonably certain date, eroding sales in both the "but for" and actual world, and implying that significant increments to damages may not exist beyond that date.

Reliability of Market Forecasts

Forecasts of the future size of the market opportunity are critical for damages claims based on lost future profits. Expert testimony on economic and business issues can assist with the evaluation of the forecasts used by the parties and the expert may also need to construct a forecast.

One argument commonly made is that sales, under the assumption of commercially reasonable efforts, are adequately set out in the

business plans and market forecasts prepared in the course of business, and that a failure to meet those forecast sales levels is both *prima facie* evidence of the lack of commercially reasonable efforts and the "but for" benchmark against which damages are to be measured. There are various problems with this approach. Most fundamentally, it is inherently based on assumptions that may not be reasonable. For example, the forecast may have been based on certain assumptions regarding the product, competitors, and the marketplace that did not come to pass, irrespective of the performance of commercially reasonable efforts. Similarly, the forecast may not have anticipated events that did occur and which were independent of an obligation to provide commercially reasonable efforts.

For these reasons, it may be desirable to have the expert prepare a forecast based on the standard approaches used in the industry. In the pharmaceutical industry, a "bottom-up" forecast may be prepared using past data on population, disease incidence, treatment rates, and projected values for each of these that can be tested against any forecast materials provided by the parties.

Discount Rate

Estimates of damages anticipated in the future should be discounted to the date of injury at a rate which accounts for the time value of money and the risks to which the future profits are exposed. This rate is the cost of capital appropriate for the business at issue. Companies may have internal estimates of the cost of capital that they use for evaluating their investment opportunities. To the extent that a cost of capital may be designed to accomplish a variety of corporate objectives, the cost of capital that the company typically uses would not necessarily be specific to the present value calculation for the dispute at issue. For example, the cost of capital that a company uses may be expected to be used to assess investments in all of its different lines of business. Accordingly, it may not be appropriate to use that cost of capital to estimate the present value of lost profits for the dispute in question.

A generally accepted approach is to collect financial data for companies in the same business as that which gives rise to the lost profits claim. With this data, standard financial methods can be used to determine the cost of capital appropriate to the dispute and specific to the risks applicable to the lost profits claim.

Conclusion

The evaluation of liability and damages issues in commercial contract disputes can be facilitated through expert evidence on business and economic issues. An assessment of commercially reasonable efforts is inherently specific to the circumstances at issue, and that is done relative to standard business practices and good business judgment. Further, evaluating damages in these contract disputes entails comparing actual performance with performance under the assumption of a different level of effort, requiring a careful consideration of the mechanism through which effort is translated into market outcomes. Knowledge and experience in the industry, along with scholarly literature concerning the relevant business issues, can be indispensable in putting forward an effective case.

Note

The views expressed herein are those of the author and do not reflect or represent the views of Charles River Associates or any of the organisations with which the author is affiliated.



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Andrew Tepperman is a vice president in CRA's Life Sciences Practice. Dr. Tepperman has considerable experience conducting economic analyses in intellectual property and antitrust litigation matters as well as in the context of other commercial disputes. His work has encompassed a variety of industries, including pharmaceuticals, biologics, medical devices, telecommunications, and computer hardware and software. He has provided expert testimony in Canadian and U.S. court proceedings.

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