Global Arbitration Review

The Guide to Damages in International Arbitration

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Damages in Life Sciences Arbitrations

Gregory K Bell, Andrew Tepperman and Justin K Ho[1]

Introduction

At a conceptual level, many of the methodologies discussed elsewhere in this volume apply equally to arbitrated disputes in the life sciences sector. The goal of the damages inquiry in this sector is the standard one: to restore the claimant to the financial position it would have achieved had the improper conduct not occurred. Standard approaches are used to attain this goal, namely determining the claimant's 'but-for' profits at each point in time during the damages period and subtracting from these the claimant's actual profits (if any). The differences between these amounts are then brought forward (in the case of past damages) or discounted back (in the case of future damages) to the relevant date (often the date of the hearing, or the expected date of the award), using appropriate interest and discount rates. As we articulate in this chapter, however, there are some complexities to damages calculations in the life sciences industries that are worthy of further discussion.

The chapter is organised as follows. The next section provides a brief overview of salient characteristics of the life sciences sector, with a focus on the biopharmaceutical industry. We then outline some of the main types of disputes that are heard in life sciences arbitrations. Following this, we discuss some of the life sciences-specific aspects of common analyses that are used to determine damages in these types of disputes.

Industry overview

Many of the companies in the life sciences industries are multinationals, operating on a global scale with respect to the discovery, production, marketing and sale of products

1 Gregory K Bell, group vice president, leads Charles River Associates' global life sciences practice, Andrew Tepperman is a vice president in the practice and Justin K Ho is an associate principal in the practice. The views expressed herein are the views and opinions of the authors and do not reflect or represent the views of Charles River Associates.

promoted for human health. These products are generally grouped as diagnostics, medical devices and pharmaceuticals. Our discussion will focus on prescription pharmaceuticals and the biopharmaceutical industry; many of the insights, however, are equally applicable with respect to damages issues involving diagnostics or medical devices.

Research and development

The value chain for the biopharmaceutical industry is composed of three principal functions: research and development (R&D), manufacturing, and sales and marketing. A principal characteristic of the industry is the long-term, high-cost, high-risk endeavour that is R&D. It is suggested that it takes more than seven years for a new drug to be discovered and brought to market, that only one in 10,000 substances that begins the development journey emerges as a marketed pharmaceutical and that only one in five marketed pharmaceuticals earn enough to cover the hundreds of millions of dollars that tend to be associated with the R&D costs of new pharmaceuticals.[2] The R&D function tends to extend from the basic and applied lab research related to identifying a potential pharmaceutical compound, to pre-clinical testing and development work, and finally through to clinical trials in humans.

Prior to product approval, the last step in the development process involves an extensive and exhaustive summary of the development work and results that is packaged as submission dossiers for regulatory approval to market the product in different countries. Regulatory approval leads to indications and usage instructions on country-specific product labels.[3] Additionally, there may be price negotiations and negotiations regarding reimbursement by the country's public health system or private insurers. Launch of the product, however, does not necessarily mean the end of R&D focused on the product. There may be ongoing efforts to explore new indications, address significant side effects, and develop new formulations.

R&D is the primary value driver of the pharmaceutical industry. Products are the scarce resource and thus it is the intellectual property developed through the R&D process that captures the residual profits generated by sales. Manufacturing capacity and sales representatives may be contracted, thus they only need to be rewarded with normal profit margins; any margin that remains accrues to the intellectual property that led to the product in the first place.

Manufacturing

Broadly speaking, two types of manufacturing processes characterise the production of pharmaceuticals. Most pharmaceuticals are pills or tablets, taken orally and generally dispensed at a retail pharmacy. For these products, manufacturing tends to be relatively well understood: there is primary manufacturing of the active pharmaceutical ingredient (API)

2 Hay et al., 'Clinical development success rates for investigational drugs,' *Nature Biotechnology*, 32:1, 2014, pp. 40-51; Joseph DiMasi and Henry Grabowski, 'The Cost of Biopharmaceutical R&D: Is Biotech Different?' *Managerial and Decision Economics*, 25, 2007, pp. 469-479; Vernon et al., 'Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model,' *Health Economics*, 19:8, 2010, pp. 1002-1005.

3 Note that indication approval and associated usage instructions for one country need not imply a similar approval in other countries.

and then secondary manufacturing to formulate and package the tablets. In contrast, most of today's high-priced pharmaceuticals are biologics. These tend to be injected or infused and may be administered by a medical professional. The production processes for biologics tend to be less standard and significantly more expensive.

Marketing

Once priced and approved for marketing in a country, the pharmaceutical is ready to be launched. The launch of a pharmaceutical tends to be an expensive process, initially focused on raising awareness of the product, generating trial and finally habituating usage by prescribing physicians.[4] As a result, it is not unusual for marketing costs to represent a high percentage of sales, and may even exceed sales in the first year or two of a product's launch.

The principal marketing tactic is the use of sales representatives who visit prescribing physicians to educate them about the product. This activity is known as 'detailing' the product. For detailing to be effective, it is critical that the sales representatives visit the right types of physicians and deliver the right message regarding appropriate use of the product with the right patients at the right time.[5] As a result, effort is spent on segmenting the physicians and patients and testing the messages so as to determine the best use of the detailing activity. It is important to note that sales representatives typically promote more than one product. Often, they will be responsible for promoting three products on a detail; the product in first position tends to dominate the time with the physician; the product in second position tends to be used as a reminder for the physician; and the product in third position often warrants only a sample drop.

From a marketing and branding perspective, one tends to consider two types of pharmaceuticals: acute care and chronic care products. Acute care products, such as antibiotics, are typically taken for only a short period of time so as to address or cure a condition. Chronic care products, such as blood pressure medications, are to be taken much longer, often for the remainder of the patient's life. As a result, utilisation of chronic care products may be less volatile than utilisation of acute care products.

Life cycle

Over time, pharmaceutical products tend to move through a life cycle. Initially, sales are low as significant marketing effort is expended to build awareness and generate trial for the product. Sales tend to climb through the growth phase of the life cycle as opinion-leading physicians promote use of the product and prescribing becomes habituated among targeted physicians. During maturity, sales grow more slowly and marketing efforts tend to be reduced; sometimes detailing for the product becomes no more than a delivery of product samples. Decline may come about for a variety of reasons. The product may be eclipsed by a next generation of therapeutics or patent protection may expire and the product becomes subject to generic or biosimilar competition. In decline, there may be no marketing and promotional support for the product; to the extent that there is continued product use, it

4 This is the awareness, trial, usage (ATU) model of sales.

5 Appropriate physician targeting is usually of principal importance; for example, it is not likely that there will be much value in detailing an Alzheimer's dementia product to a cardiologist.

tends to be as a result of ingrained physician prescribing habits and brand loyalty among patients for chronic care products.

Once the patent or some other form of market exclusivity expires, generic products (or biosimilars for biologics) may be marketed. As generics and biosimilars are essentially copies of original branded products, they do not require such large, risky investments in R&D, but they still require regulatory approval.[6] Generic products comprise the same chemical entity but are sold without the benefit of the original brand name; they do not need clinical trials to prove safety and efficacy, they need only show that they are bio-equivalent to the related branded product. Generics are seen as interchangeable for the related brand and tend to compete to be the version of the product dispensed at the pharmacy. As a result, they may not be marketed directly to physicians; instead, generics may rely on the awareness and habituated prescribing practices that the brand built over time. In slight contrast, biosimilars (because of the more complex nature of biologics) are not exactly the same chemical entity as the related branded product. As a consequence, they rely on limited clinical trials to show safety and efficacy that is sufficiently similar to the branded product. Biosimilars may not be approved as interchangeable with the original branded product; as a result, they may be branded themselves and marketed to physicians on their own. Because of these differences, biosimilars are not expected to offer as large a price discount and may account for a smaller share of sales than may be the case for generic products.

Data

The biopharmaceutical industry is replete with data regarding product sales and associated marketing efforts. Sales may be tracked on a weekly basis and one is often able to discern shares of unit sales among competing products. Publicly available unit price data are considerably less accurate. Most pharmaceuticals have list prices that tend to vary by country, but the net price that a pharmaceutical manufacturer ultimately may realise is typically not reported to the data companies. There also tends to be a fair amount of data regarding marketing efforts; there are audits that measure detailing activity, sampling, journal advertising and medical education. As a result, companies are often able to measure themselves against their competitors with respect to unit sales and associated marketing efforts. In contrast, there is little publicly available data regarding research and development and manufacturing costs, other than what may be reported at an aggregate level in a company's financial disclosures.

Collaborations and disputes

Collaborations in the pharmaceutical industry enable companies to seek partners with complementary sets of expertise in different phases of drug development, commercialisation and geography. As such, collaborations and related contractual arrangements pervade the pharmaceutical value chain. As examples, in R&D, companies license intellectual property to others to continue development and commercialisation, or companies may enter co-development agreements and jointly agree to pursue development and commercialisation. Companies may also outsource various aspects of the R&D function, contracting with

6 Regulatory issues regarding generics and biosimilars tend to be country-specific.

others to perform certain types of analyses or to manage their clinical trials. In manufacturing, companies may contract with others to develop and scale up the manufacturing process, or they may outsource all or part of the manufacturing process. In marketing, there are co-marketing and co-promotion agreements. In a co-marketing agreement, another company markets the same product under a different brand, recording its own sales; in co-promotion relationships, two companies agree to jointly market the product but only one records the sales. In other circumstances, companies may grant to others the right to commercialise the product in a certain geography or for a certain indication. In addition, companies may contract for sales representatives. All of these types of collaborations and contractual relationships may give rise to disputes, including early or otherwise inappropriate termination of the agreements. Typically, damages from these disputes tend to involve lost profits as a result of unrealised or delayed opportunities.

Commercially reasonable efforts

Many of the disputes that plague collaborations and related contractual arrangements tend to involve the execution of commercially reasonable efforts (CRE) or some variant thereof.[7] Whether it is a co-development, co-marketing, co-promotion or other type of collaboration or related contractual engagement, contracting is limited in its ability to define and articulate performance requirements for all types of situations. To be successful, the parties need to be able to respond appropriately to the environment. In this respect, there is no substitute for the sound exercise of professional judgment regarding strategic choices in the development and commercialisation of pharmaceuticals. Thus, these collaborations and types of contractual engagements tend to impose an obligation for the performance of commercially reasonable efforts, often defined as efforts that may be reasonably expected given the drug's potential, stage of development, and other market circumstances, including competitor activity. CRE thus encompass a range of appropriate strategic alternatives. Typically, there is no one right answer with respect to what constitutes CRE; if there were, the parties could have contracted for the performance of those specific services. In these types of disputes, the arbitral tribunal typically must determine whether the CRE obligation was met and if not, what are the efforts that would be considered commercially reasonable and what are the damages that result.

Intellectual property

Parties in the biopharmaceutical industry frequently enter into contracts involving access to intellectual property rights. In some cases, parties may choose to resolve intellectual property infringement and damages disputes via arbitration, rather than through the more conventional national court system.

Arbitrated damages inquiries involving intellectual property tend to be categorised into those involving the royalty base (the volume of sales deemed to incur royalty obligations) and the royalty rate payable per unit. With respect to the royalty base, for example, parties

7 For example, Sucampo and Takeda entered arbitration in 2010 due to Sucampo's allegations that Takeda's lack of sufficient marketing of Amitiza had led to poor sales (Siddiqui, Z., 'Sucampo seeks Takeda talks after losing legal battle,' Reuters, 6 July 2012).

to a licensing agreement may dispute the inclusion of sales in certain geographies or for certain indications (approved uses) of the biopharmaceutical product at issue. Disputes may also extend to what future products and developments are covered by the agreement and what limitations are placed on the companies pursuing follow-on products or research.[8]

Various circumstances can arise that require tribunals to make a determination of the applicable royalty rate. For example, a contract may specify a framework for determining royalty rates assuming certain conditions hold. The most favoured nation clause is common in licensing agreements, and may allow the licensee to obtain a lower royalty rate in light of royalty rates charged by the licensor to other parties.

Investment treaty claims

Investment treaties provide a framework to allow for fair and equitable treatment of private investment by investors in host states. Pharmaceutical companies make significant investments in the development of their products, including manufacturing and research facilities. As such, companies may argue that such assets should be considered 'investments' under international treaties and given due rights. As an example, regulatory decisions have significant impacts on the timing and extent of a pharmaceutical product launch. Investment treaty claims provide a framework for foreign companies to challenge state regulatory decisions and adjudicate disputes in arbitration.[9]

Damages considerations

As noted above, damages analysis in the biopharmaceutical industry proceeds by comparing how well off a claimant would have been but for the improper conduct. Typically, a partial characterisation – or at least a description – of this 'but for' world is an outcome of the theory of liability in the case; for this reason, it is critical that liability and damages theories are mutually consistent. For example, in a dispute concerning contractual performance or CRE, a particular liability theory may lead to the conclusion that activities undertaken by the respondent were insufficient. Key questions for damages include: (1) What would constitute a 'sufficient' level of activities? and (2) How would the changed level of activity translate to sales and profits?

Damages related to lost sales

To assess damages as a result of lost sales, it is necessary to identify the improper conduct, then determine conduct that would be considered appropriate, and finally consider the

8 For example, Genentech and Biogen Idec entered arbitration beginning in 2006 to resolve a dispute on what follow-on products to their successful Rituxan product Genentech could pursue independently ('Biogen Idec Announces Conclusion of Arbitration with Genentech,' Biogen Press Release, 16 June 2009).

9 For example, Apotex initiated a NAFTA arbitration proceeding against the U.S. seeking damages due to a FDA import ban from 2009 to 2011 ('NAFTA Tribunal Dismisses Apotex Claims,' U.S. Department of State, Office of the Spokesperson, 27 August 2014). As another example, in 2009 Servier initiated claims against Poland resulting from Poland's decisions not to renew marketing authorisations for certain Servier products (Les Laboratoires Servier, SAA, Biofarama, SAS, *Arts et Techniques du Progres SAS v. Republic of Poland*, UNICITRAL, Final Award, 14 February 2012.).

consequent impact on incremental sales, costs and profits.[10] These situations often arise with respect to contract breaches, including a failure to execute commercially reasonable efforts, and regulatory conduct under investment treaty disputes.

First: assessing conduct

CRE provisions are intended to be a low-cost, contractually efficient mechanism ensuring that the party undertaking the obligation takes appropriate actions given the contemporaneous circumstances. 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. For these reasons, determining what level of effort would be consistent with meeting the CRE obligation is not an exact science. 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 be adjusted appropriately as the magnitude of the opportunity is revealed and the life cycle of the product progresses. From a business perspective, the standard requires efforts to be large enough that they are consistent with business practices in the circumstances, but not too large in light of the perceived profit opportunity available.

Consider the example of a co-development agreement. The party responsible for developing and launching the product will have made certain expenditures relating to clinical trials, the securing of regulatory approval or launch preparation. Where liability hinges on an allegation that certain indications (approved uses) for the drug were either not pursued, or were pursued with insufficient urgency, published data on the timing of clinical development for comparable drugs in the same or similar geographies may be used to estimate how development should have proceeded. Where the allegation is that the partner has made insufficient launch preparations, a useful benchmark for the effort level may be the commercialisation plan agreed upon by the parties (subject to adjustment for any subsequent unanticipated changes in the market environment) or data regarding the actual marketing and promotion efforts surrounding the launches of potentially competing products or other appropriate analogues.

With respect to manufacturing, efforts in terms of production planning and investment in manufacturing capacity can be considered in relation to standard industry practices. Investments in highly specific manufacturing capacity may be perceived as unduly risky until there is a strong basis to conclude that regulatory approval is reasonably likely. Similarly, the competitive environment into which a product is expected to launch affects manufacturing capacity decisions. If the drug is first-in-class, demand is likely to ramp up as experience with the product and commercialisation efforts take root, allowing for a ramp-up in manufacturing capacity synchronised with (or leading) product uptake. For products expected to launch in therapeutic areas with similar products already available, demand will often be more established and easier to forecast, reducing the risk attendant to significant capacity investments at launch.

10 An exception would be a circumstance in which the expert is instructed to assume a particular level of effort(s) as a direct consequence of the liability theory.

Regarding marketing, a properly executed promotional strategy should result in a share of voice (based on sales representative meetings with doctors and other promotion initiatives) that leads to prescribing behaviour. Share of voice (SOV) places the detailing effort in the context of other competitors in the marketplace who would be presumed to be executing CRE 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 products promoted by the company's sales force.

The appropriate effort level should be attuned to the product opportunity, the stage in the life cycle 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 life cycle 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 SOV in order to generate awareness, secure trial and build share for the product. Data regarding efforts put forth on behalf of other products or analogues may provide indicators of CRE, after adjusting for market potential, stage of life cycle and competitiveness of the marketplace.

Second: determining unit sales impact

Given 'but for' conditions, the next question is: how would these conditions translate to marketplace outcomes, particularly with respect to incremental sales and incremental profits? Some may attempt to base 'but for' sales on initial forecasts and sales plans of the parties; such an approach, however, is unlikely to have anticipated and accounted for factors that may have been beyond the control or influence of the parties, including competitor behaviour, changes in treatment paradigms and shifts in disease incidence. Rather, the mechanism that links efforts, revenues and costs should be explicitly characterised, if possible.

Consider a co-development agreement. It may be alleged that failure to exert CRE led to a decision to not pursue development of certain indications for the drug in question, with the result that marketing for these indications may be delayed. To be a plausible source of damages, CRE would 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. Should this condition be satisfied, the damages model should provide a link between the lack of CRE and the alleged delay in indication approval, including the likelihood and timing of approval and the associated costs.

Regarding marketing collaborations, the mechanism linking efforts to sales and costs might be modelled as deriving from 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 influences the share of market (SOM) that a seller could capture. Given the role that awareness and trial plays in the prescribing of pharmaceuticals, the stock of accumulated promotional effort on behalf of a product may have a bearing on the influence of the flow of SOV. 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 physicians have received.

The relationship between SOV and SOM may be determined based on market data, and supported by reference to the relevant academic and professional literature. Based on these data, it may be possible to construct a model of the effects that the accumulated stock of past detailing effort and the flow of current detailing effort would have on SOM. The modelling here would not have to incorporate the full analytical complexity that appears in the academic literature; typically, it would be 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 SOV would have differed had CRE been pursued, what would have been the costs of that additional effort, and how (and when) SOM would have reacted.

Third: calculating incremental profits

Incremental revenues

Once the incremental volume of lost unit sales has been determined, the lost incremental revenues need to be calculated. For relatively small increments of unit sales, the average net price that was realised at the time is likely to be an appropriate approximation of the net revenue per unit that would have been realised. To the extent that there is an expectation of a relatively large volume of lost unit sales, it may be appropriate to consider any consequent anticipated effects on net price. The economics of the pharmaceutical industry, however, in which a physician determines the product to be used, a third party pays a significant share of the price of the product and the patient directly benefits from the consumption of the product, tends to lead to circumstances in which incremental changes in product volume may not imply incremental changes in product price.

Incremental manufacturing costs

Incremental unit sales imply incremental costs associated with manufacturing and marketing. There are two principal issues associated with the incremental costs of manufacturing pharmaceuticals. The first concerns fixed costs and variances, elements of the cost accounting system that the claimant may be using. Like other manufactured products, pharmaceuticals are typically assigned a standard cost of production; these standard costs tend to be updated on an annual basis.[11] Standard costs, however, typically include an allocation of fixed and sunk costs (such as facility rent or depreciation, respectively) that would not be incurred if more units of the product were produced. As such, it is important to determine the *incremental* costs of manufacturing the product (such as raw materials) and not assess and undervalue damages based on the *average* costs of manufacturing the product. Further, it may be important to assess the costs incurred at the time, in case the standards were set such that material variances from the standard costs (such as an unanticipated increase in the cost of raw materials) were actually incurred.

The second issue regarding manufacturing cost estimates in assessing damages resulting from lost unit sales of pharmaceutical products concerns transfer pricing. Because of the global nature of the pharmaceutical industry and the value of the intellectual property

11 Bulk API is likely to cost the same on a global basis, but secondary manufacturing costs could differ based on the product presentations that are approved for sale in a particular country.

represented by the R&D that led to the discovery of a pharmaceutical product, many multinational pharmaceutical companies use transfer pricing agreements among their subsidiaries. Typically, these agreements are designed to ensure that those subsidiaries involved in manufacturing receive a reasonable return on their manufacturing efforts and those involved with marketing receive a reasonable return on their marketing efforts. As noted above, the remainder of the profits tends to accrue to the owners of the product-based intellectual property that led to the ability to generate the profits for the subsidiaries in the first place. As a result, the transfer pricing 'cost' that may be associated with importing a product for sale in a country would include not only an allocation of fixed and sunk manufacturing costs, but also an allocation for the return on intellectual property that led to the discovery of the product. Thus, to the extent that a damages assessment is based on the transfer pricing cost of the product, damages would be undervalued.[12]

Incremental marketing costs

The principal incremental costs associated with marketing additional unit sales tend to be the cost of the additional samples (if any) that would have been distributed plus the cost of any additional incentive compensation for the sales representatives as a result of greater sales. In addition, it may be appropriate to consider the opportunity costs of the sales representatives. For example, as a result of lost sales, sales representative efforts may have been assigned to other products; but for the lost sales, however, that time may have been allocated to the product at issue and thus would be considered to be an incremental cost related to the lost sales. Note that some marketing costs, such as brand management, are fixed and typically invariant to lost unit sales. As a result, these types of costs typically would not be considered to be part of a lost profits calculation due to lost unit sales, unless the lost opportunity represented all sales of the product such that, but for the allegedly inappropriate activity, a brand manager would have been required.

Damages in intellectual property disputes

Disputes over royalties payable under licensing contracts can take various forms; it is not the goal of this chapter to review the approaches that may be taken for each possible scenario. Instead, we make some general observations that are applicable across a range of disputes. First, actual market transactions for the same or for comparable intellectual property are likely to yield the most reliable information on the value of a particular intellectual property asset and how that value would be shared between a licensor and licensee. Nonetheless, it is rarely appropriate to simply apply observed royalty rates – either the levels from other specific licensing agreements or averages across numerous agreements – without adjustments compensating for the particular circumstances at issue. Second, it is important to keep in mind that intellectual property assets are unique. For this reason, 'rules of thumb' such as the once-common '25 per cent rule' are not generally reliable guides to the royalty rates that should apply in a given situation.

12 The extent to which damages incurred by the global corporate entity (as opposed to the national subsidiary) are at issue in the litigation is typically a legal question.

The damages expert may be expected to offer an opinion on a royalty rate or other licensing terms that are consistent with what would have been agreed by the parties had they conducted a good faith negotiation as willing licensor and licensee. A methodology that is commonly used is analogous to the 'hypothetical negotiation' framework employed in court litigation in the United States. In this context, experts typically make reference to the 'Georgia-Pacific factors'.[13] While arbitrated disputes may not be bound to adopt the same approach, it is worth noting that the 'Georgia-Pacific factors' cover the issues of concern: what is the value of the intellectual property; how would that value have been split between the licensor and licensee; and what are the key sources of bargaining power.

Damages and sales forecasts

There are a number of circumstances that may arise in which a damages analysis calls for the use of estimated sales levels for a biopharmaceutical product when no actual data on sales are available. For example, a contract may be prematurely terminated, requiring the damages expert to estimate the level of sales that would have occurred had it continued. Another example might be in an investor-state treaty arbitration in which regulatory authorisation is either improperly revoked or has failed to be granted.

It may be asserted that sales are adequately set out in the business plans and projections. Whether this is appropriate is likely to depend upon the rationale for development of the projections, the assumptions used, and the extent to which the projections appropriately incorporate actual market events. For example, the forecast may have been based on certain assumptions regarding the product, competitors, and the marketplace that did not come to pass. Similarly, the forecast may not have anticipated events that did occur and that were independent of the allegedly inappropriate activity that is otherwise at issue.

For these reasons, it may be preferable to prepare a projection of 'but for' sales based on standard approaches used in the biopharmaceutical industry. A 'bottom-up' forecast of sales in the product category may be prepared using past data on population, disease incidence and treatment rates, and projections for each of these values that may be available from independent third parties. Once category sales have been projected, the 'but for' share of sales for the product can be applied. This may be determined using market research results related to anticipated physician prescribing behaviour.

13 *Georgia-Pacific Corp v. United States Plywood Corp*, 318 F. Supp. 1116, at 1121 (S.D.N.Y. 1970).

Appendix 1

About the Authors

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