DAMAGES IN INTERNATIONAL ARBITRATIONS GUIDE

FIFTH EDITION

Editor
John A Trenor

Damages in International Arbitration Guide

Fifth Edition

Editor

John A Trenor

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This article was first published in December 2022
For further information please contact insight@globalarbitrationreview.com

Published in the United Kingdom by Law Business Research Ltd
Holborn Gate, 330 High Holborn, London, WC1V 7QT, UK

www.globalarbitrationreview.com

Enquiries concerning reproduction should be sent to insight@globalarbitrationreview.com; enquiries concerning editorial content should be directed to the publisher: david.samuels@lbresearch.com

ISBN 978-1-83862-908-3

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

Acknowledgements

The publisher acknowledges and thanks the following for their learned assistance throughout the preparation of this book:

A&M GmbH Wirtschaftsprüfungsgesellschaft

Accuracy

AlixPartners UK LLP

BDO LLP

CET Group of Companies

Charles River Associates

Frontier Economics Limited

FTI Consulting LLP

HKA

Homburger AG

Intensity, LLC

King & Spalding LLP

London Business School

McDermott Will & Emery UK LLP

NERA Economic Consulting

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Vinson & Elkins RLLP

White & Case LLP

Wilmer Cutler Pickering Hale and Dorr LLP

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Preface

This fifth edition of Global Arbitration Review's *Damages in International Arbitration Guide* builds on the successful reception of the earlier editions. As explained in the Introduction, this book is designed to help all participants in the international arbitration community understand damages issues more clearly and to communicate those issues more effectively to tribunals to further the common objective of assisting arbitrators in rendering more accurate and well-reasoned awards on damages.

The book is a work in progress, with new and updated material being added to each successive edition. In particular, this fifth edition incorporates updated chapters from various authors and contributions from new authors. This edition seeks to improve the presentation of the substance through the use of visuals such as charts, graphs, tables and diagrams; worked-out examples and case studies to explain how the principles discussed apply in practice; and flow charts and checklists setting out the steps in the analyses or the quantitative models. The authors have also been encouraged to make available online additional resources, such as spreadsheets, detailed calculations, additional worked examples or case studies, and other materials.

We hope this revised edition advances the objective of the earlier editions to make the subject of damages in international arbitration more understandable and less intimidating for arbitrators and other participants in the field, and to help participants present these issues more effectively to tribunals. We continue to welcome comments from readers on how the next edition might be further improved.

John A Trenor
Wilmer Cutler Pickering Hale and Dorr LLP
November 2022

Introduction

John A Trenor[1]

There are three types of arbitrators: those who understand numbers and those who don't.

This old joke, adapted to the international arbitration community and repeated at conferences, typically receives nervous laughter from parties, counsel and experts who may have experienced innumeracy at first hand on the part of a tribunal. Yet this innumeracy is by no means limited to those who serve as arbitrators; the joke could equally be applied to those who appear as counsel and to other participants in the international arbitration community.

This book is aimed at everyone who gets the joke, whether they profess to understand numbers or not. The objective of the *Damages in International Arbitration Guide* is to help all participants in the international arbitration community – from the arbitrators to the parties to counsel and experts – understand damages issues more clearly and communicate those issues more effectively to tribunals to further the common objective of assisting arbitrators in rendering more accurate and well-reasoned awards on damages.

In the vast majority of international arbitrations, one or more parties seek damages. As such, damages are a critical component of most cases. A tribunal that misunderstands the relevant damages issues does not render justice to the parties. An award that effectively resolves the scope of liability but misunderstands, misapplies or miscalculates damages does not put the aggrieved party back in the position it would have been in if the wrongful act had not occurred. An award that seemingly takes a Solomonic approach by 'splitting the baby' or does

1 John A Trenor is a partner at Wilmer Cutler Pickering Hale and Dorr LLP.

not adequately explain the decision on damages does not typically satisfy either party and does not contribute to a favourable reputation for the arbitrators who issued the award.

Parties, and their counsel and experts, express frustration with awards that offer little reasoning on damages or, worse yet, faulty reasoning or errors in principle or calculation. Arbitrators express frustration with counsel and experts who struggle to communicate often complex damages issues clearly and effectively. Counsel and experts express frustration with each other on how best to present damages cases to tribunals that may lack quantitative backgrounds.

The idea for this book arose from discussions among members of the Global Arbitration Review editorial board, who have heard these frustrations being voiced and identified a void in the market for a guide to damages in international arbitration. This book draws on the insights of leading lawyers, experts and academics in the field to produce a work that will be a valuable desk-top reference tool for arbitrators, parties, and their advisers and counsel, when approaching damages issues in international arbitration.

This book is not intended to provide a comprehensive answer to every question. Frequently, the answer depends on the context – on the contract or treaty language, the applicable law, the arbitration agreement or rules, the facts of the case, etc. Indeed, on some issues addressed in this book, the authors (and the editor) no doubt disagree. Participation in this book is not meant to convey endorsement of the views expressed by others. However, the objective of this book, and indeed the objective of resolving disputes between parties regarding damages, is to understand better why they disagree. Is the disagreement based on differing views on what the contract, treaty or applicable law requires? Is it based on differing assumptions of the parties and their experts? Is it based on differing views of the appropriate methodology to assess and quantify damages? Or is it based on different quantitative models?

The aim of this book is to make the subject of damages in international arbitration more understandable and less intimidating for arbitrators and other participants in the field, and to help participants present these issues more effectively to tribunals. The chapters address key issues regarding various aspects of damages, identify areas of general agreement and disagreement, provide checklists and tips, and describe effective approaches to presenting and resolving damages issues. With a firm understanding of the underlying issues and the reason why the parties disagree, the arbitrators can make informed judgements on how to resolve those differences.

The book is divided into four parts.

Part I addresses various legal principles applicable to the award of damages. The chapters in this part include overviews of the civil and common law approaches to both compensatory and non-compensatory damages, and cover damages principles under the Convention on Contracts for the International Sale of Goods, contractual limitations on damages, principles for reducing damages, such as mitigation, and damages principles in investment arbitration. The authors of these chapters are counsel from leading international arbitration firms and legal academics.

Part II addresses various procedural issues regarding damages and the use of damages experts, including bifurcation, evidentiary issues such as document disclosure, and techniques and approaches to maximise the effectiveness of expert assistance on damages. The authors of these chapters are also counsel from leading international arbitration firms.

Part III addresses various approaches and methods for the assessment and quantification of damages. It includes an overview of damages and accounting basics, quantifying damages for breach of contract, the income approach (discounted cash flow methodology) and determining the weighted average cost of capital, the market approach (comparables), the asset-based approach, taxation and currency issues, interest, costs, and the use of econometric and statistical analysis. The authors of these chapters are experts from leading expert practices, and economic and financial academics.

Part IV addresses damages issues specific to certain industries or those that cut across multiple industries. These chapters include overviews of damages issues in energy and natural resources arbitrations, construction arbitrations, life sciences arbitrations, mergers and acquisitions and shareholder arbitrations and intellectual property arbitrations. The authors are again experts from leading expert practices and counsel from leading international arbitration firms.

In addition to the hard copy version of this book, the content is also available on the Global Arbitration Review website, with additional online materials identified by the authors. Online access is available to subscribers at www.globalarbitrationreview.com/insight/guides.

Many individuals have contributed to making this book a success and deserve thanks. First and foremost, the authors of the chapters have shared in the vision of helping participants in the international arbitration community understand damages issues better. Their valuable contributions help to achieve this goal.

The professional team at Global Arbitration Review and its publisher, Law Business Research, have worked tirelessly at all stages of the process, from conception of the idea, through the editorial process, to publication.

This book would also not have been possible without the ideas and support of numerous current and former colleagues at Wilmer Cutler Pickering Hale and Dorr LLP.

Global Arbitration Review's *Damages in International Arbitration Guide* will continue to be updated in future editions. Contributing authors will be encouraged to update existing chapters and new authors will be invited to contribute additional chapters. If readers wish to see further topics included or existing topics addressed in more detail, please bring them to my attention or to the attention of Global Arbitration Review. We also welcome comments from readers on how the next edition might be improved.

I share the hope of Global Arbitration Review that this book and future editions will form a valuable contribution to the field of international arbitration and that, in the future, the joke that there are three types of arbitrators (or counsel, or others) – those who understand numbers and those who don't – no longer resonates.

Part IV

Industry-Specific Damages Issues

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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 guide 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, 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 first 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 aspects of common analyses specific to life sciences that are used to determine damages in these types of disputes.

1 Gregory K Bell is a group vice president, Andrew Tepperman is a vice president and Justin K Ho is a principal at Charles River Associates.

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 promoted for human health. These products are generally grouped as diagnostics, medical devices and pharmaceuticals. Our discussion focuses 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 earns 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 laboratory research relating to identifying a potential pharmaceutical compound, to pre-clinical testing and development work, through to clinical trials in human beings.

Before product approval, the last step in the development process involves an extensive and exhaustive summary of the development work and results, which 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 negotiations on price and 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 continuing efforts to explore new indications, address significant side effects and develop new formulations.

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2 Hay et al., 'Clinical development success rates for investigational drugs', *Nature Biotechnology*, 32:1, 2014, pp. 40–51; DiMasi and Grabowski, 'The Cost of Biopharmaceutical R&D: Is Biotech Different?' in *Managerial and Decision Economics*, 25 (2007), pp. 469–79; Vernon et al., 'Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model', *Health Economics*, 19:8 (2010), pp. 1002–05.

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

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, and thus 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

In broad terms, 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 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 trials and finally habituating use 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 within 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

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.

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 pharmaceutical products: those for acute care and those for chronic care. Acute care products, such as antibiotics, are typically taken for only a short time to address or cure a condition. Chronic care products, such as blood pressure medications, are to be taken for much longer, often for the remainder of a patient's life. As a result, utilisation of chronic care products may be less volatile than that 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 during 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 new 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 or promotional support for the product; to the extent that there is continued product use, it tends to be as a result of ingrained prescribing habits of physicians and brand loyalty from patients for chronic care products.

Once a patent or 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, but 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

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

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. 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 weekly and it is often possible 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 R&D 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 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 market the product jointly 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 these types of collaborations and contractual relationships may give rise to disputes, including those involving early or otherwise inappropriate termination of 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 judgement 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, an arbitral tribunal typically must determine whether the CRE obligation was met and, if not, the efforts that would be considered commercially reasonable and the damages that result.

7 For example, Sucampo and Takeda entered arbitration in 2010 as a result of 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).

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 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 the future products and developments that are covered by the agreement and the limitations that 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 that 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 these assets should be considered 'investments' under international treaties and given due rights. As an example, regulatory decisions have a significant effect on the timing

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).

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 in the Introduction, 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 what would constitute a 'sufficient' level of activities, and how the changed level of activity would translate to sales and profits.

Damages relating to lost sales

To assess damages as a result of lost sales, it is necessary to identify the improper conduct, then determine the type of conduct that would be considered appropriate, and finally consider the consequent effects 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 action given the contemporaneous circumstances. The party's efforts are expected to be in line with what similarly situated businesses would normally do, relative to

9 For example, Apotex initiated an arbitration under the North American Free Trade Agreement (NAFTA) against the United States seeking damages due to an import ban by the US Food and Drug Administration from 2009 to 2011 ('NAFTA Tribunal Dismisses Apotex Claims,' US 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*, United Nations Commission on International Trade Law, Final Award, 14 February 2012.).

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

the commercial gains that could be expected from successful efforts. For these reasons, determining the level of effort that 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 had 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. If the allegation is that the partner has made insufficient launch preparations, a useful benchmark for the level of effort may be the commercialisation plan agreed 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 increase as experience with the product and commercialisation efforts take root, allowing for a surge 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.

Regarding marketing, a properly executed promotional strategy should result in a share of voice (SOV) (based on sales representatives' meetings with doctors and other promotion initiatives) that leads to prescribing behaviour. 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 level of effort 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 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 the effect on unit sales

Given 'but for' conditions, the next question is how these conditions would translate to marketplace outcomes, particularly with respect to incremental sales and incremental profits. Some may attempt to base but-for sales on the parties' initial forecasts and sales plans; this 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 not to 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 SOV for the product. The key empirical relationship here relates 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 of awareness and trial 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 factors 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 consumption of the product – tends to lead to circumstances in which incremental changes in product volume may not imply material 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). As with other manufactured products, pharmaceuticals are typically assigned a standard

cost of production; these standard costs tend to be updated annually.[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 may be 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 represented by the R&D that leads 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

11 Bulk active pharmaceutical ingredients are likely to cost the same globally, but secondary manufacturing costs could differ based on the product presentations that are approved for sale in a particular country.

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.

of lost sales, the efforts of sales representatives 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 an incremental cost relating 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 as part of a lost profits calculation owing 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 about 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 situation. Instead, we make some general observations that are applicable across a range of disputes.

First, actual market transactions for the same, or 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 a 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. For example, a licensor with an oncology product may have licensed intellectual property for research in other therapeutic areas; these agreements would not necessarily inform the terms of a licence for oncology that might lead to the development of a competing product. 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.

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] Although arbitrated disputes may not be bound to adopt the same approach, it is worth

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

noting that the *Georgia-Pacific* factors cover the issues of concern: the value of the intellectual property; how that value would have been split between the licensor and the licensee; and 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 on 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 relating to anticipated prescribing behaviour of physicians.

APPENDIX 1

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Gregory Bell leads CRA's global life sciences practice. As an expert witness, he frequently testifies on damages in intellectual property, finance and antitrust litigation in courts and arbitration proceedings in North America, Europe, Asia and Australia. Dr Bell's business consulting engagements focus on the economics of business strategy, working with firms to develop sustainable competitive advantages in specific product markets. He has led and consulted on numerous projects concerning game theory and competitive strategy, global launch strategy, product pricing and positioning, capital budgeting and real options, and cost-benefit analyses. Dr Bell is a chartered accountant in Canada and earned his MBA and PhD in business economics from Harvard University.

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ISBN 978-1-83862-908-3