THE INVESTMENT TREATY ARBITRATION REVIEW

SIXTH EDITION

Editor
Barton Legum

THE LAWREVIEWS

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PREFACE

This year's edition of *The Investment Treaty Arbitration Review*, like that of last year, goes to press under particular circumstances. Measures to contain the covid-19 pandemic around the world have confined many authors to quarters. Despite these constraints, the authors of this volume have delivered their chapters. The result is a new edition providing an up-to-date panorama of the field. This is no small feat given the constant flow of new awards, decisions and other developments over the past year.

Many useful treatises on investment treaty arbitration have been written. The relentless rate of change in the field rapidly leaves them out of date.

In this environment of constant change, *The Investment Treaty Arbitration Review* fulfils an essential function. Updated every year, it provides a current perspective on a quickly evolving topic. Organised by topic rather than by jurisdiction, it allows readers to access rapidly not only the most recent developments on a given subject, but also the debate that led to and the context behind those developments.

This sixth edition adds new topics to the *Review*, increasing its scope and utility to practitioners. It represents an important achievement in the field of investment treaty arbitration. I thank the contributors for their fine work in developing the content for this volume under the difficult conditions that continue to prevail today.

Barton Legum
Dentons
Paris
May 2021

Part VIII

Industries

Chapter 42

INVESTMENT TREATY DISPUTES IN THE LIFE SCIENCES INDUSTRY

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

I INTRODUCTION

In its global scale and economic impact, the life sciences industry presents unique considerations for investment treaty arbitrations. Recently, the covid-19 pandemic has pushed the life sciences industry even further to the forefront of international commerce. The race to develop and test vaccines and therapeutics, the extent of state support for research and procurement, and the global competition for access to limited supplies of personal protective equipment (PPE), diagnostics, treatments, and now vaccines has highlighted the interconnected nature of the industry and the significance of government policy and regulation. Although the life sciences industry has not been a prominent contributor of investment treaty arbitrations in the past, we expect to see more of this activity in the future as the industry continues to evolve. In this paper, we focus on notable aspects of the life sciences industry and the issues that they may raise for investment treaty arbitrations.

II UNIQUE FEATURES OF THE LIFE SCIENCES INDUSTRY

We consider several features of the life sciences industry that are likely to raise significant issues for investment treaty arbitrations. We discuss these issues primarily through the context of pharmaceuticals, but medical devices and diagnostics pose many similar concerns.

a Much of the value generated by the industry tends to be concentrated in intellectual property that is the result of high-cost, high-risk endeavours focused on the research and development (R&D) of new products. As with the development of covid-19 vaccines, these endeavours may leverage state-sponsored research or may benefit directly from state-sponsored investment.[2]

b Patents, and thus a state's patent regime, have a significant impact on value in the industry. Branded pharmaceuticals that are patent-protected may exhibit large price-cost margins; once patent protection expires, however, generic versions of the

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

2 For example, the United States established Operation Warp Speed to accelerate the covid-19 vaccine development (Operation Warp Speed Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges, US Government Accountability Office, February 2021, www.gao.gov/assets/gao-21-319.pdf). Similarly, in the United Kingdom, the government provided funding for the vaccine developed by Oxford University and AstraZeneca ('Funding and manufacturing boost for UK vaccine programme', University of Oxford, 18 May 2020, www.ox.ac.uk/news/2020-05-18-funding-and-manufacturing-boost-uk-vaccine-programme).

branded product may be introduced at significantly lower prices. With respect to generic products, relatively more of the product value tends to be concentrated in manufacturing and local distribution functions and assets.

c States control access to national markets through regulatory approvals for marketing, for both branded and generic products.

d Production tends to be integrated on a global basis but subject to state-specific regulatory requirements. Tax considerations coupled with scale economies, high price-to-weight ratios, and long shelf life leads to extensive intra-company trade in life sciences, but state-specific trade barriers tend to preclude arbitrage at the finished product level.

e Many states play a significant role in product pricing and procurement, often by virtue of their position as payers for healthcare. As a result, states may negotiate the degree of access to a geographic market subject to pricing approval.[3]

f For many products in the industry, the only need for state-specific investment is related to local marketing and distribution functions and assets. From an industry perspective, investments in R&D and manufacturing do not have state-specific requirements beyond access to specialised labour.

This set of issues leads to tensions for relationships between the industry and the state that may manifest in investment treaty arbitrations. The high price-cost margins, enabled by patent protection and required to motivate costly, risky and ultimately sunk investments in R&D, generate the potential for opportunistic behaviour by states. States want to encourage R&D to yield new products to enhance health and productivity; once those products are developed, however, states would prefer to expand low-cost access to the products, particularly if the state ends up as a principal payer for the products. For their part, once life sciences companies develop a product, they seek to tailor pricing and distribution specific to a country or region and maximise global returns.

III PAST INVESTMENT TREATY ARBITRATIONS IN LIFE SCIENCES

We've seen some of these issues play out in investment treaty arbitrations in the life sciences industry. The following table is a list of investment treaty arbitrations involving life sciences companies that were initiated between 2000 and 2020, as identified from publicly available sources.

3 For example, in the UK, the National Health Service (NHS) determines access and negotiates discounts with manufacturers from the list price of drugs and bases its assessments of fair prices according to cost-effectiveness analyses ('Briefing paper: Who decides the price and availability of NHS medicines?', Centre for Health and the Public Interest, March 2019, https://chpi.org.uk/wp-content/uploads/2019/03/Who-decides-the-price-and-availability-of-NHS-medicines-Mar19.pdf; 'Drug Pricing', Houses of Parliament Parliamentary Office of Science & Technology, Number 364, October 2010, www.parliament.uk/globalassets/documents/post/postpn_364_Drug_Pricing.pdf).

Case Name	Year initiated	Treaty	Seeking relief from	Status/Outcome
Italy v. Cuba[*]	2003	Cuba–Italy BIT (1993)	Discriminatory treatment by Cuba of multiple Italian businesses, including of an Italian pharmaceutical company concerning long-term sales contracts.	Judgment for Cuba on all claims (2008)
Apotex v. US (I)[†]	2008	NAFTA (1992)	Delayed launch of claimant's generic version of Zoloft due to 6-month generic exclusivity.	Judgment for state on jurisdiction (2013)
Apotex v. US (II)[‡]	2009	NAFTA (1992)	Delayed launch of Claimant's generic version of Pravachol due to 6-month generic exclusivity.	Judgment for State on jurisdiction (2013)
Servier v. Poland[§]	2009	France–Poland BIT (1989)	Withdrawal of marketing authorisation for claimant's pharmaceutical products in Poland following harmonisation with EU regulatory standards.	Judgment for claimant (2012)
Minnotte and Lewis v. Poland[¶]	2010	Poland–US BIT (1990)	Bankruptcy allegedly caused by interference with loans for building the first blood plasma fractionation plant in Poland.	Judgment for state on the merits (2014)
Merck v. Ecuador[‖]	2011	Ecuador–US BIT (1993)	Local court judgment arising from the sale of claimant's pharmaceutical manufacturing facility.	Judgment for claimant (2018)[**]
Apotex v. US (III)[††]	2012	NAFTA (1992)	Halt on claimant's importation of generics and hold on its pending ANDAs based on an allegedly discriminatory inspection of its manufacturing plant.	Judgment for state on res judicata (2014)
Eli Lilly v. Canada[‡‡]	2012	NAFTA (1992)	Invalidation of claimant's patents on Strattera and Zyprexa under the utility doctrine.	Judgment for the state on the merits (2017)
Hourani v. Kazakhstan[§§]	2015	Kazakhstan–UK BIT (1995) & Kazakhstan–US BIT (1992)	Expropriation and liquidation of claimant's pharmaceutical company by Kazakhstan.	Settled (2020)[¶¶]
Novartis v. Colombia[‖‖]	2016	Swiss–Colombia BIT (2006)	Proposed mandatory 44% price reduction on imatinib in Colombia.	Withdrawn (2016); no public reports of settlement
Gilead v. Ukraine[***]	2016	US–Ukraine BIT (1996)	Launch of generic version of Sovaldi in Ukrainian market.	Settled (2017)
Pfizer v. Ecuador[†††]	2017	US–Ecuador BIT (1993)	Local court judgments against claimant in favour of a generic manufacturer of sildenafil.	Withdrawn (2017); no public reports of settlement
Qatar Pharma v. Saudi Arabia[‡‡‡]	2019	OIC Investment Agreement (1981)	Repudiation of long-term sales contracts and refusal to pay for products already received.	Pending
Santamarta v. Venezuela[§§§]	2020	Spain–Venezuela BIT (1995)	Seizure of SM Pharma's manufacturing facilities by Venezuelan government.	Pending

* Cabrera, Orlando F., 'TDM IACL Case Report: The Republic of Italy v. The Republic of Cuba – Ad Hoc Arbitration – Final Award – 15 January 2008', Transnational-Dispute-Management.com, www.transnational-dispute-management.com/legal-and-regulatory-detail.asp?key=27830 (Cabrera 2008).
† *Apotex Inc. v. The Government of the United States of America*, ICSID Case No. UNCT/10/2, Award on Jurisdiction and Admissibility (14 June 2013) (Apotex v. US (I & II)), p. 12.
‡ *Apotex v. US (I & II)*, p. 12.
§ *Les Laboratoires Servier, S.A.S., Biofarma, S.A.S., Arts et Techniques du Progres S.A.S. v. Republic of Poland*, Final Award (14 February 2012).
¶ *David Minnotte and Robert Lewis v. Republic of Poland*, ICSID Case No. ARB(AF)/10/1, Award (16 May 2014).
‖ *Merck Sharp and Dohme (I.A.) Corp. v. The Republic of Ecuador*, Notice of Arbitration (29 November 2011).
** Charlotin, Damien and Luke Eric Peterson, 'The Merck v. Ecuador Award (Part One): Arbitrators Wave Away Jurisdictional Objections – Including on Exhaustion – and Warn that Non-Compliance with Interim Orders could Aggravate Treaty Breach', *Investment Arbitration Reporter*, 27 March 2018.
†† *Apotex Holdings Inc and Apotex Inc v. United States of America*, ICSID Case No. ARB(AF)/12/1, Award (25 August 2014), p. I.2.
‡‡ *Eli Lilly and Company v. Government of Canada*, Case No. UNCT/14/2, Final Award (16 March 2017).
§§ 'Case Details: Devincci Salah Hourani and Issam Salah Hourani v. Republic of Kazakhstan (ICSID Case No. ARB/15/13)', ICSID, at https://icsid.worldbank.org/cases/case-database/case-detail?CaseNo=ARB/15/13.
¶¶ Sanderson, Cosmo, 'Hourani Brothers Settle with Kazakhstan', *Global Arbitration Review*, 9 June 2020.
‖‖ Williams, Zoe, 'Investigation: as Colombia pushes for cancer drug price-cut and considers compulsory licensing, Novartis responds with quiet filing of an investment treaty notice', *Investment Arbitration Reporter*, 30 November 2016.
*** Peterson, Luke Eric and Zoe Williams, 'Pharma Corp Withdraws Investment Arbitration after Ukraine Government Agrees to Settlement of Dispute over Monopoly Rights to Market Anti-Viral Drug', *Investment Arbitration Reporter*, 16 March 2017; Sinichkina, Lana *et al.*, 'Ukraine: Protecting Investments through Entry Agreements Between Pharma and Government', PharmaExec.com, 27 June 2017, www.pharmexec.com/view/ukraine-protecting-investments-thr ough-entry-agreements-between-pharma-and-government.
††† Lentner, Gabriel M, 'Another IP-Related International Investment Arbitration Looming', *Transatlantic Technology Law Forum Newsletter on Transatlantic Antitrust and IPR Developments*, 30 January 2018.
‡‡‡ 'Qatar Pharma and Ahmed Bin Mohammad Al Haie Al Sulaiti v. Kingdom of Saudi Arabia', *IAReporter.com*, www.iareporter.com/arbitration-cases/qatar-pharma-and-ahmed-bin-mohammad-al-haie-al-sulaiti-v-saudi-arabia/.
§§§ 'Raimundo Santamarta Devis v. Bolivarian Republic of Venezuela', *IAReporter.com*, www.iareporter.com/arbitration-cases/raimundo-santamarta-v-venezuela/.

Several of the matters identified in the table relate to the intellectual property that is at the heart of value in the life sciences industry. Three of the matters (*Eli Lilly v. Canada*, *Gilead v. Ukraine* and *Pfizer v. Ecuador*) appear to have been driven by a company seeking to preserve its patent-protected position for a product in a national market; two others (*Apotex v. US (I)* and *Apotex v. US (II)*) were driven by a company seeking to accelerate generic entry into a national market. Relatedly, the relatively high price-cost margin that tends to be associated with patent-protected branded pharmaceuticals, coupled with the high profile of oncology products, drove the issue in the *Novartis v. Colombia* matter regarding Gleevec,[4] one of the first cancer therapeutics to be administered orally. As discussed below, the increasing number of relatively highly priced specialty pharmaceuticals could lead to more disputes associated with pharmaceutical pricing.

Other regulatory issues were at the heart of two matters: the *Servier v. Poland* matter focused on regulatory approvals for access to the Polish market and the *Apotex v. US (III)* matter focused on manufacturing compliance for access to the US market. The other six matters might be characterised as more 'standard' investment treaty arbitrations, with the state being accused of adversely affecting the value of in-country assets and investments by the pharmaceutical company. Four of the matters (*Minnotte and Lewis v. Poland*, *Merck v. Ecuador*, *Hourani v. Kazakhstan* and *Santmarta v. Venezuela*) relate to in-country manufacturing facilities; two of the matters (*Italy v. Cuba* and *Qatar Pharma v. Saudi Arabia*) relate to in-country distribution capabilities.

As we consider the future of investment treaty arbitrations, we might expect to see more disputes focused on patent rights as states strive for access to new products at lower cost. For example, compulsory licensing had been a threat that states had used to some

4 Gleevec is sold as Glivec in Colombia and in certain other countries in the world.

effect with pharmaceutical companies to secure access to highly valued products.[5] There was some discussion of compulsory licensing when states were faced with demand following Gilead's launch of Sovaldi and the first opportunity for a cure of hepatitis-C.[6] Some of the recent discussion around covid-19 vaccines has once again raised the spectre of compulsory licensing.[7] Pricing and regulatory disputes also may become more common if states do more to leverage their control over access to their national markets.

IV FUTURE ISSUES FOR INVESTMENT TREATY ARBITRATIONS IN LIFE SCIENCES

Continued scientific and clinical innovation, however, will perhaps be the most significant factor for the future of investment treaty arbitrations in life sciences. These innovations are introducing new issues likely to have a unique impact on disputes in the life sciences industry.

a The ability to protect trade secrets is becoming more significant for life sciences. As an example, with the advent of biologics, manufacturing and product characterisation concerns have a much greater impact on profitability. This trend will continue and likely accelerate as the industry continues to commercialise cell and gene therapies.

b More products, particularly gene therapies and therapies for rare diseases, are coming to market without the expansive clinical trials typically required to confirm efficacy. For rare diseases, the problem is the number of patients available for clinical trials; for curative gene therapies, the duration of efficacy is unknown. This is leading to more access contracts for these therapies where pricing is contingent on subsequent proof of efficacy.

c Development of autologous therapies, such as skin tissue replacement, where a patient's own cells are extracted, treated, and then re-implanted, is leading to the development of regional centres of excellence to perform these procedures. For rare conditions, these centres of excellence are likely to service patients from more than the host country.

d Cyber security concerns regarding implantable medical devices, from insulin pumps to pacemakers and defibrillators, will become more significant as these devices increasingly rely on software and are networked to share data.

5 For example, lower income countries issued compulsory licences for HIV-AIDS antiretroviral medicines in the 2000s (e.g., Zambia issued a compulsory licence for lamivudine, stavudine and nevirapine in September 2004 (Compulsory Licence No. CL 01/2004, Republic of Zambia Ministry of Commerce, Trade and Industry, www.cptech.org/ip/health/c/zambia/zcl.html). See also, Urias, Eduardo and Shyama V Ramani, 'Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence', *Journal of International Business Policy*, 3, 2020, pp. 367–384, https://link.springer.com/article/10.1057/s42214-020-00068-4.

6 For example, Gilead was negotiating access and pricing for Sovaldi with Malaysia in 2016. When negotiations failed, Malaysia announced its decision to license government use and manufacture of the product; in turn, Gilead announced that it would allow some generic versions to be sold locally. (See Kintada, Lekhya, 'Compulsory Licensing for Hepatitis C Medication in Malaysia', 10 April 2019, PublicCitizen, www.citizen.org/news/compulsory-licensing-for-hepatitis-c-medication-in-malaysia/).

7 Gebrekidan, Selam and Matt Apuzzo, 'Rich Countries Signed Away a Chance to Vaccinate the World', *New York Times*, 21 March 2021; Nasos Koukakis, 'Countries Worldwide Look to Acquire the Intellectual Property Rights of Covid-19 Vaccine Makers', CNBC.com, 22 January 2021, www.cnbc.com/2021/01/22/countries-look-to-acquire-the-ip-of-vaccine-makers-to-fight-pandemic.html.

e Comprehensive genomic profiling (CGP) will become a reality for standard medical care. One of the promising aspects of this diagnostic tool is the ability to reference data from hundreds of thousands to millions of patients in order to make diagnoses and treatment recommendations. The privacy implications for states may be significant.

National policy and regulation are likely going to emerge as some of the most significant commercial challenges associated with the scientific advances that are happening in life sciences. Current policy and regulatory regimes were developed and have been optimised for an industry that was dominated by mass-market blockbuster pharmaceuticals that were self-administered. These regimes, however, are ill-equipped to address the challenges that are going to be posed by personalised medicine involving specialty products with new infrastructure requirements for diagnosis and administration.

As a result, the coming years in the life sciences industry are sure to see many more disputes highlighting policy and regulatory issues, with implications for investment treaty arbitration. How will health technology assessment (HTA) regimes adapt to consider new technologies and grant appropriate access? What will be the forum for the inevitable disputes over contingent pricing contracts with state payers? What will be the mechanism for state payment for access to out-of-state centres of excellence? How will states police cyber threats for implantable devices? How will privacy laws adapt to enable the full benefit of CGP? These are just some of the challenges that we see for the future of investment treaty arbitration in the life sciences industry.

V DAMAGES IN LIFE SCIENCES DISPUTES

Valuing the loss or delay of a commercial opportunity poses some unique issues in life sciences because of the features of the industry noted above. We will highlight two considerations of likely significance regarding investment treaty arbitration: accounting for the likelihood of product approval and appropriately using product analogues as benchmarks for sales performance from other countries or therapeutic areas.

i Probability of product approval

A dispute may involve a lost product opportunity, potentially because of delays in development initiatives. In such circumstances, the claim may involve a valuation of the product opportunity and a concern is whether the opportunity was too speculative, perhaps because of the high failure rates associated with pharmaceutical development, to yield compensable damages through an investment treaty arbitration.

There is an abundance of data on the development and regulatory approval process in the pharmaceutical industry, particularly with respect to typical success rates regarding approval in the United States. There are statistics regarding development time-in-stage and the likelihood of progressing to successive phases of clinical development and ultimately regulatory approval for pharmaceutical products in general, by therapeutic category, and by

type of product.[8] A standard problem often stems from the use of these data in combination with the cost of capital or discount rate appropriate to estimate the present value of a potential product opportunity.

The likelihood of regulatory approval and the discount rate used to estimate the value of future cashflows generated by a potential new pharmaceutical are two distinct concepts that are often confused. The first, the likelihood of regulatory approval, is based on technical issues – does the product offer an appropriate balance of safety and efficacy. The second, being the discount rate that would be appropriate to use to value future cashflows to be generated by the pharmaceutical, is subject to standard economic and financial concerns associated with the riskiness of those cashflows. As has been noted in more than one article and text on the issue, one should take care to not confuse the technical likelihood of success with the riskiness of cashflows that would be associated with the product.[9]

Nonetheless, many stock market analysts (and even some internal company estimates) use a shortcut to value new product opportunities in the pharmaceutical industry. These analyses will simply use a higher discount rate as a means (albeit inappropriate) of combining the likelihood of regulatory approval with the standard approach to discounting future cashflows. The suggestion is that the value of the asset in development can be approximated by combining the likelihood of regulatory approval with the more standard cost of capital used to discount future cashflows. This is incorrect and can lead to wildly inappropriate assessments of value from the perspective of the award of damages that would be paid as the result of an investment treaty arbitration.

Further, the use of a higher discount rate, ostensibly to account for the likelihood of regulatory approval, may have the effect of converting an arguably speculative opportunity into one that appears appropriate for damages consideration. Consider a product in Phase II clinical trials. On average, such products only have a 15.3 per cent likelihood of regulatory approval, indicating that it is significantly more likely than not that this product opportunity will never make it to market.[10] Attempting to value damages based on the assumption that the product does make it to market and just using a higher discount rate to account for the uncertainty associated with the likelihood of regulatory approval, however, does not convert what may be a speculative opportunity into an appropriate damages valuation.

Does this mean that the loss of the product opportunity is too speculative on which to base a damages claim? It does not, but it does mean that an approach based on the present value of future cashflows that explicitly considers regulatory approval may be inappropriate for products at an early stage of development. Instead, for products at such an early stage of development, it may be more appropriate to consider actual licences or acquisitions of other product opportunities in the same therapeutic area and at a similar stage of development. Metrics derived from an assessment of these potential comparables may provide more appropriate support for an estimate of damages.[11]

8 See, for example, Clinical Development Success Rates 2006-2015, *Biomedtracker*, June 2016, www.bio.org/sites/default/files/legacy/bioorg/docs/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

9 For example, see US Congress, Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, Washington, US Government Printing Office (1993), pp. 8–9; Brealey, Richard, et al., Principles of Corporate Finance, Tenth Edition, New York, McGraw-Hill/Irwin (2011), p. 224.

10 Clinical Development Success Rates 2006-2015, *Biomedtracker*, June 2016, p. 9.

11 See BioSciDB.com for a database of licensing and acquisitions in the pharmaceutical industry.

ii Benchmarking with product analogues

A dispute also may involve delayed entry to a national market or absence from a national market for a period of time. The damages inquiry typically focuses on the profits that would have been earned but for the associated delay or the absence. Often, one measure of those profits is taken from performance of the asset in other countries that were not affected by the conduct at issue. This can be an appropriate methodology in life sciences disputes as well, but particular care must be taken to consider compensating adjustments that may be required to account for differences between the markets. These differences may be because of differences in disease prevalence, differences in medical practice, differences in the provision of and payment for healthcare, or differences in the regulatory regimes, all with potentially associated differences in prices, competitors and product profitability.

Forecasting the quantity of products sold will depend on appropriate assumptions (and associated regulatory decisions) in the absence of the dispute. Other factors may also be important, including estimates of patient population, current and expected future competition (alternative products, generics), the life cycle of the affected drugs, manufacturing capacity and the duration of any associated intangible assets. Price assumptions can be particularly problematic, especially with respect to states that have a significant influence on price. It is critical to determine the appropriate price and associated regulatory decisions that would prevail in the absence of the disputed state actions and to ensure that the assumed price is consistent with the other market assumptions.

Regarding lost profits, one also must consider the costs associated with foregone sales. The launch of new drugs is typically an expensive process with companies focused on first raising awareness of the product, then generating initial use, before seeking habituated prescribing and use by satisfied physicians and patients. As a result, investments in marketing often represent a high percentage of sales in the initial years of launch, potentially generating accounting losses. An appropriate determination of lost profits must account for such factors. For example, it generally would not be appropriate to assume profit margins in the initial years of product launch would apply to a forecast over the product lifecycle; for successful products, the profit margin often increases after the initial period of launch investments.

Transfer pricing also may be a concern. Due to the global nature of the industry and the value of the intellectual property generated through R&D, many multinational pharmaceutical companies use transfer pricing agreements 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. The remainder of the profits tends to accrue to the owners of the intellectual property associated with the product. As a result, the transfer pricing 'cost' that may be associated with importing a product for sale in a country would include not only compensation for the manufacturing function, but also an allocation of return on the intellectual property associated with the product. Thus, to the extent that a damages assessment is based on the transfer pricing cost of the product paid by a subsidiary, damages would be undervalued with respect to the consolidated entity.[12]

12 The extent to which damages borne by the global corporate entity (as opposed to the national subsidiary) are at issue in the dispute may be a legal question.

VI CONCLUSION

The continued evolution of the life sciences industry, featuring rapid and revolutionary technological change, is sure to provoke new issues in investment treaty arbitrations. This chapter focuses on some of the relatively unique aspects of the life sciences industry and the challenges they may pose for investment treaty arbitrations. In addition, we review some of the damages issues likely to arise in investment treaty arbitrations, particularly as they relate to product opportunities in the life sciences industry.

Appendix 1

ABOUT THE AUTHORS

GREGORY K BELL

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Gregory Bell is a group vice president at CRA. 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 to 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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Andrew Tepperman is a vice president at CRA, based in Toronto, Canada. He specialises in providing economic and damages analyses for clients involved in arbitration and litigation proceedings. Dr Tepperman has assessed damages in a wide range of disputes, including intellectual property, breach of contract and antitrust matters. He has also performed economic analyses of liability issues in arbitration proceedings, including assessment of commercially reasonable efforts, and antitrust litigation matters, including analyses of market definition and market power. His work has encompassed a variety of industries, including

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