



CRA Insights

Life Sciences

CRA Charles River
Associates

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2022 Year in Review: Litigation

Dear Clients and Friends,

Our return to office in 2022 coincided with a year of intense activity in our dispute resolution engagements and other areas of the practice. Wins at trial included a successful defense of Bard against antitrust tying allegations and successful support of J&J's restructuring efforts as it addressed talc product liability cases (later addressed on appeal). Arbitration work included assessments of global collaboration and distribution agreements, analyses of commercially reasonable efforts, and quantum associated with licensing agreements.

We also helped our clients secure significant settlements, including our assistance with ViiV's patent litigation involving HIV products that resulted in a \$1.25 billion settlement. 2022 was a year of growth for other areas of the Life Sciences practice, as well. Our Strategy consulting efforts notably included some new work on the global commercialization challenges for cell and gene therapies and new work on pricing and access for high-cost, rare disease therapies. Our Policy consulting work included a focus on health equity and the life sciences implications of the US Inflation Reduction Act. See our high-level summary of some of the IRA implications in this recent [three-part series](#).

Finally, I am happy to report that our practice itself grew as well in 2022! bioStrategies Group, a Chicago-based consultancy focused on life sciences strategy consulting, [joined us](#) late in the year, providing 17 new colleagues and broadening our geographic scope and subject-matter depth. Our Payor and Economic Research speaker series continue to broaden our network of friends and experts and invigorate our efforts to bring innovative ideas to our clients.

We are happy to share this update, which describes representative engagements from this past year and summarizes our ideas and activities.

Thank you for the trust you place in us and I look forward to being able to see many of you (in person) this year.

Sincerely,

[Gregory K. Bell](#)

Group Vice President and Global Practice Leader

Antitrust

There are still some patent disputes with allegations of reverse payment, but as science continues to advance and life sciences products become increasingly more complex and customizable, we expect to see more disputes associated with access to technologies and tying and related practices.

Sample engagements:

Successful defense against alleged tying: The autumn trial of *C.R. Bard v. AngioDynamics* provided insight into competitive dynamics for medical devices. AngioDynamics claimed that C.R. Bard had illegally tied its peripherally inserted central catheters (PICCs) to its PICC navigation and location devices, thereby foreclosing AngioDynamics' PICCs. CRA Senior Consultant, **Professor Fiona Scott Morton** testified regarding antitrust liability, opining that Bard sold PICC products in a single market rather than separate markets and that there were no anticompetitive effects associated with the tie; **Dr. Gregory Bell** testified regarding damages, opining that AngioDynamics had not shown that it would have made any additional sales absent the alleged tie. On October 6, the jury found for C.R. Bard. Professor Scott Morton was supported by **Dr. Jeffrey Prisbrey**; Dr. Bell was supported by **Dr. Justin Ho** and **Ms. Maia Otermin**.

Damages for a reverse payment settlement: On behalf of a party to a reverse payment settlement, CRA consultants were asked to calculate damages to a state Medicaid program. Our analysis included calculation of the statutory Medicaid rebate under different scenarios and backcasting reimbursement amounts. **Dr. Bell** was supported by **Mr. Archan Ruparel** and **Ms. Erin McDermott**.

Events

State bar associations remain interested in pharmaceutical pricing and the effects of competition, especially for how those dynamics might differ between small and large molecule therapies. In September, **Ms. Erin McDermott** and **Mr. Archan Ruparel** presented on "An Overview of Prescription Drug Competition" to the New York State Bar Association Antitrust Law Section.

Dr. Annabelle Fowler presented her paper "Promotion, Pricing, and Utilization Implications of Pharmaceutical Line Extensions" at the 11th Annual Conference of the American Society of Health Economists.

Commercial Agreements

We will continue to see growth in disputes regarding commercial agreements, often related to commercially reasonable efforts associated with product development and commercialization. Many of these disputes will have an international dimension due to the significance of local market expertise. Accordingly, arbitration is likely to remain a favored venue for resolution. Below, we discuss a range of sample engagements, reflecting the diversity of commercial disputes for which CRA is routinely engaged in the life sciences industry.

Sample engagements:

Alleged breach of an agreement to commercialize: CRA was retained by the respondent in an arbitration concerning the alleged breach of an agreement to commercialize a dermatology product. At issue was whether the respondent, a major pharmaceutical company, had used

commercially reasonable efforts in its launch and commercialization of the product and its eventual decision to divest the product to another company. **Dr. Gregory Bell** testified at the hearing concerning the respondent's promotional efforts, concluding that commercially reasonable efforts were exercised. In addition, Dr. Bell addressed the damages assessment proffered by claimant's expert. Dr. Bell was supported by **Dr. Andrew Tepperman** and **Mr. Archan Ruparel**.

Practices and procedures of nonprofit technology transfer offices: CRA was retained by the United States government to provide opinions on the typical practices and procedures of nonprofit technology transfer offices in a breach of contract dispute at the U.S. Court of Federal Claims. **Dr. Sean Sheridan** testified regarding technology transfer practices with respect to the management of material transfer and clinical trial agreements.

Termination provision of a collaboration agreement: CRA was retained by the respondent in an arbitration dispute concerning whether a clause in the termination provision of the collaboration agreement required the respondent to continue paying royalties following the termination of the agreement. CRA consultants were asked to opine on whether the claimant's interpretation of a clause in the termination provision was consistent with generally accepted accounting principles and the claimant's own publicly reported financial statements. **CRA Senior Consultant Michael Caprio, CPA**, submitted an expert declaration regarding SEC reporting requirements; **Dr. Gregory Bell** submitted expert testimony regarding accounting principles and the claimant's financial statements. Mr. Caprio was supported by **Ms. Allison Wiese**; Dr. Bell was supported by **Mr. James Donohue**, **Dr. Daniel Shack**, and **Mr. Billy Muttiah**.

Alleged breach of vaccine development agreement: CRA was retained by the claimant in an arbitration regarding a breach of contract dispute relating to the development of a vaccine product. **Dr. Sean Sheridan** testified regarding lost investment and losses attributable to the diminution in value of the vaccine candidate due to delayed clinical development and approval.

Alleged breach of a non-compete clause: CRA was retained by the claimant in an arbitration dispute concerning the alleged breach of a non-compete clause in an agreement to distribute a prescription women's health product in Asia. **Dr. Gregory Bell** provided an expert report regarding the quantum of lost profits suffered by the claimant because of the alleged breach. Dr. Bell was supported by **Dr. Daniel Shack** and **Mr. Billy Muttiah**.

Alleged breach of license agreement: CRA was retained by the claimant in an arbitration regarding the breach of a license agreement relating to pharmaceutical manufacturing technology. **Dr. Sean Sheridan** testified regarding the interpretation of certain licensing provisions and quantified damages.

Events and publications

Dr. Gregory Bell moderated an internationally recognized panel of arbitrators and practitioners for the Global Arbitration Review webinar titled "**Collaboration Agreements in Life Sciences – International Arbitration Issues**." Panelists offered insights into governing law issues, liability, damages, and the efficient use of arbitrations to resolve issues associated with collaborations and efforts clauses in life sciences.

Drs. Gregory Bell, Andrew Tepperman, and Justin Ho authored a chapter titled "**Damages in Life Sciences Arbitrations**," in Global Arbitration Review's *Damages in International Arbitrations Guide*, 5th edition.

Financial

We expect to see more contingent value rights disputes on the horizon as CVRs can be a very effective means of bridging value differences for pipeline products in life sciences due to the uncertainty regarding the timing and likelihood of product approval and uptake.

Sample engagement:

Talc litigation: CRA was retained on behalf of LTL Management LLC, the Debtor in a bankruptcy case to opine on the impact that talc tort litigation had on the Johnson & Johnson Consumer Inc. business unit from which it was created following a divisional merger.

Dr. Gregory Bell testified assessing the impact of the mass tort litigation on the current and future financial viability of the corporate entity and its ability to compete in the marketplace. Claimants sought dismissal of the bankruptcy filing. U.S. Bankruptcy Judge Michael B. Kaplan denied Claimant's motion to dismiss and found in favor of the Debtor. Recently, the Third Circuit ruled that LTL's Chapter 11 filing was not made in good faith, without addressing the corporate restructuring. Dr. Bell was supported by **Dr. Peter Rankin**, **Mr. Billy Muttiah**, **Ms. Erin McDermott**, and **Mr. Archan Ruparel**.

Intellectual Property

Intellectual property is the lifeblood of Life Sciences. The practice continues to do a lot of work related to irreparable harm, commercial success, and damages.

Sample engagements:

Commercial success of heart failure medication: On behalf of plaintiff, CRA was retained to assess the commercial success of a heart failure medication and the nexus between that success and the patents-in-suit. **Dr. Gregory Bell** submitted an expert report that assessed the product's sales, sales growth, and profitability in a competitive environment that included numerous alternative treatments. Consideration of clinical research, clinical guidelines, and marketing literature supported a conclusion of commercial success attributable to the patents-in-suit. Finally, we also considered whether earlier patents deterred and "blocked" competitor research into the product in the context of typical drug development timelines. Dr. Bell was supported by **Dr. Justin Ho**.

Commercial success of pre-operative skin sterilization products: CRA was retained by the petitioner in an IPR proceeding at the Patent Trial and Appeal Board to determine whether there was evidence of commercial success for certain pre-operative skin sterilization products. CRA consultants also conducted analyses demonstrating that the commercial performance of the product did not change following the issuance of the challenged patent. **Dr. Sean Sheridan** testified in the matter, supported by **Ms. Maia Otermin**.

Lost profits and reasonable royalties in HIV medication: CRA was retained by plaintiffs in a patent litigation regarding HIV medications. Under the guidance of **Mr. Ray Sims** as the testifying expert, the CRA team assessed lost profits and reasonable royalties. Following the exchange of expert reports and depositions, the parties reached a multi-billion dollar settlement. Mr. Sims was assisted by **Dr. Andrew Tepperman** and **Ms. Taylor Rubinato**.

Damages for a patent dispute in rare disease: CRA was retained by the plaintiff to provide an expert opinion on damages in a patent dispute involving antibody technologies. **Dr. Gregory**

Bell provided an opinion on the reasonable royalty that would emerge from the hypothetical negotiation. Following the exchange of expert reports and depositions, the parties reached a settlement in excess of \$500 million. Dr. Bell was assisted by **Dr. Andrew Tepperman** and **Ms. Taylor Rubinato**.

Valuation of contributions to codeveloped intellectual property: CRA was retained to serve as a neutral advisor to the Tribunal in an international arbitration involving a licensing dispute between two agricultural sciences companies. As the neutral advisor, **Dr. Sean Sheridan** provided a flexible valuation model, expert reports, and hearing testimony concerning the value of the parties' relative contributions to the development of novel herbicide technology. Dr. Sheridan was assisted by **Ms. Ivy Guo**.

Events and publications

Dr. Sean Sheridan and **Mr. Archan Ruparel** spoke about economic considerations of IP litigation settlements involving biosimilars on the ABA podcast "Our Curious Amalgam" (**Episode 172**).

Dr. Sean Sheridan contributed to the "2021 Global Life Sciences Royalty Rates and Deal Terms Survey," released in May 2022 by the Licensing Executive Society. **Dr. Sheridan** was a speaker at the **LES-hosted webinar** to discuss the survey results.

In addition, **Dr. Sheridan** delivered a number of presentations on intellectual property issues related to life sciences, including:

"Determining Royalty Rates for University IP: A Webinar Workshop for Tech Transfer and IP Professionals" Technology Transfer Tactics, Webcast, 2022.

"LES@BIO 2022, Royalty Rates & Deal Terms Survey" BIO International Convention, San Diego, CA, 2022, Co-presenter.

Drs. Gregory Bell, Justin Ho, and Andrew Tepperman authored a chapter titled "**Damages in International IP Arbitration**," in Global Arbitration Review's *The Guide to IP Arbitration*, 2nd edition.

About CRA's Life Sciences Litigation

CRA's life sciences litigation support services are grounded in a comprehensive understanding of pharmaceutical, biotechnology, medical device, and diagnostic markets. For more than 30 years, our experts have consulted with major life science companies, law firms, and regulatory agencies around the globe. We provide clients with the industry and analytical expertise needed to solve our clients' most complex issues.

CRA has a reputation for delivering rigorous analysis and expert testimony. Economic expertise is complemented by experience assisting life sciences companies with business and policy issues. This combination allows CRA to provide effective expert testimony and support. Learn more at www.crai.com/industries/life-sciences/litigation/.

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