

At A Glance

Economic Issues in Vaccine Litigation

Unlike traditional pharmaceuticals, which are synthesized chemicals, vaccines are biologics, which are manufactured, extracted, or semi-synthesized from biological sources. This distinction has legal and economic implications because biologics often face different market pressures from competition, are generally covered by a larger number of patents, and face unique production challenges, all of which can impact litigation, particularly fact and expert discovery.

A wide variety of litigation may focus on vaccines and vaccine-related intellectual property, including questions of competition, patent infringement and trade secrets, government sourcing, valuation and pricing, and insurance coverage. NERA Economic Consulting has significant relevant expertise in each of these.

Areas of Expertise



Intellectual Property

The anticipated development and rapid scaling of vaccine production for COVID-19 vaccines may raise concerns related to ownership of

intellectual property, licensing disputes, compensation, and royalty disputes, among others. NERA has experience in litigation and arbitration matters involving economic issues around IP licensing, including disputes over the ownership of IP, licensing, compensation, and royalties, as well as the assessment and valuation of biopharma patents, trademarks, and trade secrets and their impact on future competition.



Antitrust

NERA consultants routinely conduct economic analysis related to antitrust scrutiny in the biopharmaceutical industry, including evaluating mergers, acquisitions,

and joint ventures; analyzing the pro- and anti-competitive effects of bundling and other types of pricing practices; evaluating class certification and market definition; analyzing patent settlements; and determining damages in alleged monopolization and collusion cases. NERA also has experience advising whether an innovator's pharmaceutical product was priced excessively using various benchmarks.



Public Sector

The unique circumstances surrounding the COVID-19 pandemic and governments' responses to it could create a host of allegations of fraud, abuse, and illegal government support for the industry. With a deep understanding of reimbursement institutions and the ability to manage and analyze large amounts of data, NERA's experts have experience and extensive capability to assist companies facing government investigation or federal qui tam litigation related to alleged False Claims Act violations.

NERA regularly helps companies and government institutions evaluate allegations of illegal state aid, including the identification of market failures that might justify the aid, assessment of competitive effects, the incentive effect of aid, and the risk of competitive distortions.



Valuation

NERA has experience in the valuation of BLA-licensed and developmental biologics patents and product lines in litigation, arbitration, and non-dispute settings.

Our analyses have included an assessment of both launched products and products in development, future market share pressures from potential biosimilar competitors, analysis related to licensing and cross-licensing negotiations, and an assessment of market entry by other non-infringing technologies.



Securities

NERA has extensively assessed the materiality of stock price movements in the pharmaceutical industry, using event studies and other tools from financial

economics to determine if price movements are statistically significant. NERA has statistically analyzed the internal data from clinical trials to help explain what a company could have known at different phases of the clinical trial process. NERA also has experience assessing the market efficiency of securities, in particular for biotech and other start-up firms.



Product Liability

Combining scientific analysis with behavioral economics, NERA economists have developed rigorous models to help companies size their potential exposure.

To project future vaccine-related claims filings, NERA experts estimate the size of the population potentially exposed to the vaccine, predict levels and severity of adverse events, and project the number of claims filed by those with an adverse event. Because not every injury will result in a claim, NERA experts examine historical claiming rates related to comparable vaccines and assess how those rates may change in the future. To value future claims, NERA experts analyze patterns of vaccine-related historical

settlements, use statistical analysis to extrapolate forward settlement values, and price future claims, taking into account the variability in available vaccine compensation systems and litigation costs across countries.

Experience

The following are examples of the breadth of experience NERA consultants have representing clients in the biopharmaceutical industry.

NERA analyzed a series of breach of contract claims between two biotech firms involved in vaccines and therapeutics targeting infectious diseases and autoimmune disorders.

NERA performed a rigorous analysis of each element of claimed damages to determine the proper theory under which each fell and then, based on that theory, properly quantified the damage. Claimed damages stemmed from allegations of breach of contract, trade secret misappropriation, tortious interference, and interferences with existing and prospective research projects.

NERA provided an expert report in a securities class action against Dendreon, a biotech company.

The action revolved around disclosures related to their immunotherapy for prostate cancer and pending biologics license applications. NERA worked on various aspects of the analysis for the securities case, such as assessing the materiality of various alleged misstatements the company made related to manufacturing Provenge, the cancer vaccine for which the company had a pending biologics license application and the regulatory approval process it was going through. NERA also opined on alleged 20A (insider trading) damages.

NERA analyzed the impact of news announcements related to the development of a vaccine on the stock price of a biotechnology firm.

Performing an event study, NERA found that the majority of the stock price movement could be explained by industry trends and news events about the progression of the disease, rather than by any company-specific news related to the case allegations.

NERA provided a valuation report supporting a biotechnology firm's intercompany transfer of intellectual property between two non-US subsidiaries. Our analyses included an assessment of both launched and developmental products, future market share pressures from potential biosimilar competitors, an assessment of market entry by other non-infringing technologies, and an evaluation of potential market comparable transactions.

NERA experts provided expert testimony on a merger in the medical sterilization industry, which plays a key role in the mass-delivery of vaccines. NERA provided expert report testimony on behalf of the merging parties in response to the FTC's challenge of the purchase of British sterilization services provider Synergy Health Plc Steris and Synergy Health by Steris Corp. The court agreed with NERA's economic assessments and refused the FTC's request to enjoin the merger.

NERA represented a biotechnology company in a breach of license agreement case. Representing a company that uses CRISPR technology, NERA evaluated and estimated harm due to a breach of the license agreement between the parties, to include unjust enrichment and actual damages resulting from the breach.

NERA provided an expert report in a misappropriation of trade secrets case concerning the manufacturing process of a therapeutic vaccine in clinical development. The plaintiff alleged that the defendant was able to advance clinical development by approximately a year. NERA staff calculated the amount of disgorgement damages. Since both parties were several years away from commercializing their respective products, NERA staff assessed the impact of the misappropriation with a discounted cash flow (DCF) model.

NERA provided an expert report in an antitrust case concerning monopolization of a pharmaceutical product market. The plaintiff alleged that the defendant monopolized the pharmaceutical product market by securing an exclusive supply agreement with the sole supplier of the sterilized active pharmaceutical ingredient (API). NERA assessed the relevant antitrust

market for the product-at-issue by examining both the price and non-price factors affecting competition in prescription pharmaceuticals. NERA showed that the relevant antitrust market was broader than the pharmaceutical product as evidenced by key pharmaceutical industry factors such as rebates, detailing, sampling, formulary, placement, and therapeutic substitution.

NERA provided an expert report in a patent infringement case concerning competitors with two BLA-approved products with similar indications. NERA provided an opinion on the reasonable royalty and lost profits. NERA determined whether lost profits was an appropriate measure of damages using the four Panduit factors and assessed a reasonable royalty using the Georgia-Pacific factors.

Life Sciences

NERA is a pioneer in the field of economic and statistical analysis for clients in the global life sciences industry. We are collaborating with law firms, pharmaceutical companies, medical device manufacturers, and diagnostic firms to address complex issues raised by legal disputes and regulatory challenges, devise strategies to manage tax burdens across jurisdictions, value liabilities, and advise firms on a range of economic issues related to life sciences.

Clients choose NERA because our experts have a strong history of providing independent, insightful, and comprehensive analysis and guidance in the pharmaceutical, biotechnology, medical device, and diagnostics industries. We work with the world's top law firms, life sciences companies, regulators, tax authorities, and other entities to:

- Determine the value of patents and other intellectual property, and advise firms in license negotiations.
- Consult on economic issues involving patent, product liability, mass tort, false claims, breach of contract, antitrust, securities, and trade secrets litigation, including forecasting future liabilities.
- Develop strategies to manage national and global tax exposure and address inquiries from tax authorities.

- Address competition and antitrust issues arising as part of reviews being undertaken by state, national, and global authorities, and from private litigation.
- Advise and provide expert analysis in the class certification, liability, and damages phases of antitrust, securities, and product liability class actions.
- Provide economic and statistical analysis of causation and damages in government investigations and litigation involving claims of fraud, False Claims Act, and Anti-Kickback Statute violations.
- Assist in corporate bankruptcies, complex commercial litigation, business valuations, and other securities matters.
- Respond to financial market abuse investigations and defend against enforcement actions in alleged violations of anti-corruption, fraud, and securities laws.

About NERA

NERA Economic Consulting (www.nera.com) is a global firm of experts dedicated to applying economic, finance, and quantitative principles to complex business and legal challenges. For over half a century, NERA's economists have been creating strategies, studies, reports, expert testimony, and policy recommendations for government authorities and the world's leading law firms and corporations. We bring academic rigor, objectivity, and real-world industry experience to bear on issues arising from competition, regulation, public policy, strategy, finance, and litigation.

NERA's clients value our ability to apply and communicate state-of-the-art approaches clearly and convincingly, our commitment to deliver unbiased findings, and our reputation for quality and independence. Our clients rely on the integrity and skills of our unparalleled team of economists and other experts backed by the resources and reliability of one of the world's largest economic consultancies. With its main office in New York City, NERA serves clients from more than 25 offices across North America, Europe, and Asia Pacific.

Contact

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