

At A Glance

Life Sciences Capabilities Briefing

NERA is a pioneer in the field of economic and statistical analysis for clients in the global life sciences industry. We collaborate 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. Our team delivers a deep and nuanced understanding of the institutional and regulatory structures of health care delivery that pervade disputes in these industries. We work with many of 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, kickbacks, 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; and
- Respond to financial market abuse investigations and defend against enforcement actions in alleged violations of anti-corruption, fraud, and securities laws.

The following provides more detailed background specifically covering NERA's qualifications in life sciences matters.

Pharmaceutical and Biotechnology

NERA's global team of economic, statistical, and data experts works with many of the world's leading pharmaceutical and biotechnology firms, regulators, tax authorities, and other entities to provide expert analysis and testimony across a number of disciplines.

Antitrust and Competition

In the past three years alone, NERA has represented clients in over 50 antitrust and competition matters involving pharmaceutical and biotechnology companies, including investigations before US and EU regulatory authorities, cases involving reverse payments, civil lawsuits alleging anticompetitive behavior, and pre-merger economic analysis and consulting. Our economists are well-versed in the unique competitive and regulatory issues faced by companies in the pharmaceutical and biotechnology industries and are deeply experienced in conducting the unbiased economic and statistical analysis and rigorous econometric modeling necessary to provide thoughtfully considered, highly defensible expert reports and testimony. Select examples of recent matters include cases in which our team:

- Analyzed potential antitrust liability and damages resulting from alleged monopolization in an over-the-counter medication market;
- Assisted pharmaceutical clients before US competition authorities during merger investigations;
- Provided expert analysis and testimony in a class action antitrust lawsuit against a global pharmaceutical company under Federal Rule 23 involving commonality, typicality, and the predominance of common questions related to liability and damages; and
- Analyzed the compatibility of dual-pricing schemes for the distribution of pharmaceutical products in the EU.

Intellectual Property

Over the past three years, NERA's intellectual property economists, survey experts, and social scientists have represented clients in more than 100 matters involving branded and generic pharmaceuticals, over-the-counter medications, and dietary supplements. Below are examples of recent matters:

- Appraised the value of intellectual property assets, determined reasonable royalty rates, and quantified damages in numerous patent infringement cases;
- Provided survey evidence (including survey design and analysis of results) for class action lawsuits resulting from an alleged data breach;

- Assisted counsel with a US Supreme Court brief relating to the economic effects of a potential stay of entry of a generic pharmaceutical; and
- Provided commercial success analysis for pharmaceutical clients in Hatch-Waxman ANDA matters.

Product Liability and Mass Torts

NERA experts have been analyzing personal injury and product liability issues for almost 15 years, assisting companies with projects related to product recalls, damages claims, insurance disputes, mergers and acquisitions and consumer class actions. Examples of recent matters include:

- Provided testimony in an insurance dispute involving whether the claims being made against a pharmaceutical company were related to on-label or off-label warnings;
- Forecasted future liabilities related to personal injury claims arising from the historical use of beauty products; and
- Allocated claims to insurers in pharmaceutical litigation, providing advice on how to structure settlements to maximize payments available under existing insurance policies and forecasting future claims for continuing litigation with third and fourth tier insurers once primary insurer limits were exhausted.

Securities

NERA is widely recognized as a leading provider of economic and financial analysis in securities and finance matters. Our experts work with pharmaceutical and biotechnology companies, directors and offices, regulators, and other entities in bet-the-company matters including mass torts, shareholder class actions, white collar criminal and regulatory enforcement actions, and commercial disputes. Examples of recent matters include:

- Provided analysis of materiality, loss causation, and damages for a cross-border (US-Canada) shareholder class action lawsuit;
- Represented a client in a 10b-5 case involving a biotechnology company with an orphan drug in the pipeline; and

- Designed, conducted, and reviewed results of a survey in a false advertising class action lawsuit of a food supplement manufacturer.

Transfer Pricing

NERA's global Transfer Pricing Practice provides clients in the pharmaceutical, biotechnology, cosmetics, and biologics industries with expert analysis, valuation support, and advice. Our experts frequently represent clients in matters before national and international tax authorities, serve as expert witnesses in litigation and arbitration, and provide guidance to regulatory bodies responsible for domestic and global tax policy. Examples of recent matters include:

- Provided an expert testimony in tax controversy proceedings involving a multinational pharmaceutical company;
- Prepared documentation for compliance with the terms of a cost sharing arrangement for a biotechnology research company;
- Advised a biopharmaceutical company expanding to the US on an optimal arrangement for the intangibles ownership that takes into account the group's operating model;
- Represented a European medical supply company in a tax audit challenging the level of interest rate applicable to a convertible bond held by the parent company;
- Prepared documentation of "arm's length charges" for intercompany transactions among the American and European operations of a pharmaceutical and beauty supply company;
- Reviewed and prepared a report regarding intercompany transactions of intangibles and tangible products for a global biotechnology company; and
- Performed a benchmarking study for distribution, marketing, and manufacturing activities of a pharmaceutical wholesaler.

Medical Devices and Technology

Medical device manufacturers and technology companies face a rapidly evolving regulatory and business environment, underscored by new mergers and partnerships between medical device and medical technology companies, increased regulatory scrutiny, rapid technological advancement, and growing cybersecurity threats.

Antitrust and Competition

As with any growing industry, we expect the medical device and technology fields to experience a surge in competition-related claims and antitrust concerns. NERA has provided assistance to clients involved in antitrust claims for half a century. Our experts combine institutional knowledge of the medical device market and a rigorous economic approach with a deep understanding of antitrust and competition law. The following are select examples of NERA services provided to our medical device clients:

- Competition analysis, including market definition, market power, relevant market, barriers to entry, injury to competition, and antitrust damages, in the medical equipment, device, and supply markets; and
- Evaluation of competitive impact of proposed transactions or mergers.

Intellectual Property

NERA's intellectual property economists apply thorough analysis in IP disputes to determine damages in connection with infringement and breach-of-contract claims involving patents and trade secrets for clients in the medical device industry. We also work with clients to address such issues as irreparable harm and the impact of alleged false or misleading advertising. Beyond this, our consultants work with medical device clients to value IP in connection with selling or licensing negotiations, preparing required transfer pricing documentation, obtaining advanced approval from a tax authority for the price of a particular trade flow or resolving a tax controversy. We help our clients identify portions of their IP portfolios that have value, develop strategies to manage risk, and use their IP for strategic advantage in the marketplace. The following are recent examples of our work:



- Designed and conducted surveys to address trade dress issues;
- Conducted statistical analysis for a medical device manufacturer preparing for arbitration in a National Advertising Division challenge;
- Calculated reasonable royalties, lost profits, and price erosion in patent and trademark infringement cases involving innovation in medical technology and equipment; and
- Quantified damages for medical research and development patent infringement cases.

Product Liability and Mass Torts

NERA economists work with medical device companies on projects related to product recalls, damages claims, insurance disputes, mergers and acquisitions and consumer class actions. Examples of recent matters include:

- Estimated the liability related to the implantation of artificial hips, including projecting likely failure rates and expected claiming rates;
- Estimated the liquidated value of all present and future product liability claims, including settlements and opt-outs, in a bankruptcy case involving medical devices; and
- Provided a valuation of liabilities and analysis of insurance allocation for a medical equipment company resulting from a mass silica exposure lawsuit.

Securities

NERA's securities and finance economists work with clients in the medical device and medical equipment industries to address allegations of product liability and securities fraud, to assist in resolving commercial disputes, and to manage financial, legal, and securities risks. Examples of recent matters include:

- Valued the assets of a medical device company in a bankruptcy proceeding involving claims of fraudulent transfers; and
- Provided analysis and expert testimony in a securities class action involving a medical equipment company.

Transfer Pricing

Based throughout Europe and the US, NERA's transfer pricing economists provide clients in the medical device and medical technology industries with expert analysis, valuation support, and advice on domestic and cross-border tax and valuation matters, and serve as expert witnesses in tax litigation and arbitration matters. Examples of recent work include:

- Provided expert testimony in tax controversy proceedings involving a multinational medical device company;
- Provided a policy and documentation review in light of changing medical device and accessory regulations;
- Conducted a transfer pricing analysis for a medical technology, wholesale, and retail company for its operations in the EU and Russia; and
- Performed a detailed analysis and consulted on the transfer pricing structure between the EU and US for a medical device company.

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. With its main office in New York City, NERA serves clients from more than 25 offices across North America, Europe, and Asia Pacific.

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