PHARMACEUTICAL, BIOTECH AND MEDICAL DEVICES - Overview

The pharmaceuticals, biotechnology and medical device industries face unique legal challenges. Claims of health care fraud and abuse, products liability and mass tort litigation, and consumer fraud class actions have put increased business pressures on corporate clients. The courts have seen an explosion of ANDA litigation, testing the strength of key pharmaceutical patents. Legislative challenges abound as state and federal governments look for ways to control health care costs.

Our lawyers have experience in a wide range of matters that help our corporate clients address these pressing issues and more. Members of the Practice include top-ranked trial lawyers and lawyers with advanced degrees in relevant sciences.

Products liability and class action defense. -- We have significant experience defending pharmaceutical companies in products liability, class action and mass tort litigation. We have been national counsel and regional counsel and lead counsel on over 100 individual cases. Our Practice puts a premium on developing the good company/ scientific defense. We also use prelitigation risk assessment and risk management analyses to help clients avoid or minimize the risk of litigation.

Intellectual property litigation. -- Our lawyers are skilled in trying intellectual property and and patent cases, including high-stakes ANDA litigation, as well as counseling, and patent and trademark prosecution.

Fraud and abuse counseling and litigation. -- Our fraud and abuse team includes two former United States Attorneys, former Assistant U.S. Attorneys and former SEC staff. We often advise about compliance issues and represent companies in criminal investigations and civil litigation involving issues such as anti-kickback violations and improper marketing of pharmaceutical products.

Commercial Litigation and Antitrust. -- Members of the group have represented clients in insurance coverage disputes, counseling and litigation over contract disputes, antitrust litigation, counseling on pricing and distributorship issues and impact of overseas laws.

Regulatory counseling and advocacy. -- Our lawyers counsel in SEC and FDA regulations and guidance, compliance with HIPAA patient privacy and security rules, new product approvals, post-approval marketing restrictions, incident reporting and advocating for changes to existing or proposed rules.
Transactions and licensing. -- We have represented U.S. and foreign companies in the pharmaceutical and biotech industries in divestitures, financings, license agreements, joint ventures and other commercial matters.
Our Work

Products Liability, Commercial and Antitrust

We offer a large cadre of first-chair trial lawyers who have obtained effective results in cases of significant exposure. Many of our lawyers have advanced scientific training, bringing added value to fact development and expert defenses.

Multinational Fortune 50 Pharmaceutical Company: Defense of dozens of pharmaceutical and medical device products. Roles have included national coordinating counsel, regional counsel and trial counsel. We have done extensive work in areas of science involving medicine (hepatology, endocrinology, neurology, psychiatry), epidemiology, toxicology, pharmacovigilance and risk management.

Flu Vaccine Manufacturer: National coordinating counsel for over 50 lawsuits, alleging that exposure to vaccines caused neurological delays and other injuries to children. Successful resolution based on early fact-finding and motion practice.

International Chemical and Medical Product Company: Defense of nationwide childhood vaccine litigation; member of a national team defending class action litigation involving silicone breast implants; analysis of biotechnology licensing issues.

Medical Device Manufacturer: National litigation counsel for a leading manufacturer of medical devices, defending against products liability actions involving device used in surgery.

Manufacturer of Brand-Name Prescription Drugs: Lead trial counsel in the successful antitrust defense against charges of a Sherman Act conspiracy in an eleven-week jury trial.

Pharmaceutical Manufacturer: Lead trial counsel at trial and on appeal, obtaining insurance coverage for over 1500 diethylstilbestrol personal injury cases.

Device Manufacturer: Lead counsel on insurance action obtaining coverage for business losses following hurricane damage.

International Pharmaceutical Company: Lead counsel in multinational dispute over supply of contaminated chemical used to manufacture pharmaceutical, leading to an international recall. Successful arbitration, with client receiving damages award and partial attorneys’ fees.

Major Pharmaceutical Company: Defense of multiple class action lawsuits filed by patients and insurers alleging that the company engaged in
fraudulent marketing and pricing practices.

State University: Defense of “whistleblower” lawsuits arising from liver transplant program.

Medical Device Manufacturer: Defense of multiple medical device claims involving penile implant products.

Multinational Manufacturer: Litigation risk assessment and risk management recommendations for innovative pharmaceutical at pre-marketing stage.

Development of risk assessment protocols and procedures and early warning systems for application to business lines or business products.

In addition, our attorneys have defended numerous toxic tort actions involving causation issues including issues of medicine, epidemiology and toxicology.

Intellectual Property Litigation

Jenner & Block has litigated patent infringement cases in courts all over the country. Our attorneys have experience in patent litigation, trademark, licensing, transactions and counseling, and many of our attorneys hold advanced scientific degrees. We have helped our clients with overseas enforcement or defense of patent actions, especially in Germany — the rocket docket of patent litigation in Europe — where we have significant contacts.

Examples of our attorneys’ work in patent infringement litigation include:

Representation of Johnson & Johnson subsidiary Alza Corporation regarding its patent on the chemotherapy agent, Doxil. The case was a dispute brought by one of the founders of the company that developed Doxil, claiming that he and the other plaintiff were the true inventors of the drug delivery vehicle. The plaintiffs claimed that Alza’s patent on Doxil properly belonged to them and that they were entitled to over $90 million in damages for unjust enrichment. Plaintiffs relied heavily on the apparently similar case of Univ. of Colorado v. American Cyanamid where the court awarded over $50 million in unjust enrichment. In a bench trial in the Northern District of California the Court ruled for our clients, Alza and the four inventors of the drug delivery vehicle used in Doxil, on all issues.

Representation of McNeil Laboratories in a seven-week jury trial focused on Tylenol Gelcaps. McNeil was victorious in that jury trial leading to the removal of Bayer’s product from the market, as well as a substantial damages award.

Representation of Medtronic in a successful appeal to the Federal Circuit and later obtained a favorable jury verdict, completely exonerating Medtronic from Bard’s charge of patent infringement.
OUR WORK

Representation of LaserSight Inc. in patent infringement action in the midst of licensing discussions with VISX, the industry giant in laser eye surgery, in which LaserSight achieved a settlement of the case and received a license, not only on the patent-in-suit, but on all other laser eye surgery patents in VISX’s portfolio.

Representation of McNeil-PPC, Inc. and Johnson & Johnson in an action in which Richardson-Vicks asserted a patent against McNeil and Johnson & Johnson. Obtained a judgment as a matter of law in favor of our clients, a decision upheld on appeal by the Federal Circuit.

Representation of Iolab Corporation at jury trial and on appeal in a patent infringement action brought by Pannu for alleged infringement involving the manufacture of intraocular lenses. The jury ruled in Iolab’s favor, finding no infringement on the vast majority of the accused lenses. With respect to the very few lenses that were allegedly infringing, Federal Circuit reversed the district court, holding that there was a substantial issue of invalidity based on improper inventorship and that the issue should have been submitted to the jury.

Representation of Johnson & Johnson in arbitration resulting in preservation of the company’s license to distribute erythropoietin and an 89% reduction in damages sought against company.

Representation of Chiron Corporation in litigation involving dueling patents over next generation DNA probes for identifying and quantifying human immunodeficiency virus (HIV).

Successful representation of leading manufacturer of medical devices used in LASIK surgery in defense of a patent infringement action brought by competing manufacturer.

We are experienced in negotiating and preparing contracts involving joint ventures, technology development, OEM and VAR relationships, outsourcing, the collateralization of intellectual property, and e-commerce arrangements. Our attorneys frequently handle the intellectual property aspects of mergers and acquisitions, including drafting and negotiating agreements, as well as due diligence reviews.

We are also experienced in every aspect of patent prosecution. The many Jenner & Block attorneys who are registered to practice before the U.S. Patent & Trademark Office apply their litigation, transaction and counseling experience, as well as their technical backgrounds, in drafting and prosecuting patent applications. Our patent prosecution experience includes medical devices, chemical products, electronics, manufacturing equipment and methods, aerospace, machine tools, and business methods. In trademark matters, our experience includes counseling.
clients prior to the adoption of new marks and obtaining trademark registrations in the United States Patent & Trademark Office and abroad.

Fraud and Abuse Counseling and Litigation

Our fraud and abuse lawyers have been consistently recognized as among the best litigators in the country in publications such as *Corporate Legal Times* and *The National Law Journal*. In addition, we regularly counsel firms in the health care industry on compliance with fraud and abuse, antitrust, and privacy laws, including the Anti-Kickback and Stark regulations, HIPAA and Sarbanes-Oxley.

We have substantial experience representing pharmaceutical, biotech, medical device manufacturers and other health care providers in criminal and civil matters involving fraud and abuse allegations, including:

Defense of a major pharmaceutical company in a series of class action lawsuits filed by patients and secondary insurers claiming fraud arising from the use of allegedly inflated average wholesale prices.

Defense of pharmaceutical manufacturer in *qui tam* action alleging off-label promotion of prescription drugs, kickbacks to physicians and Medicare/Medicaid fraud.

Representation of a major biotechnology company in litigation involving alleged off-label marketing and payment of kickbacks to physicians disguised as grant payments.

Representation of a prescription drug manufacturer in a grand jury investigation into allegations that it misled the Food and Drug Administration in connection with a new drug application.

Representation of a medical device manufacturer in *qui tam* litigation alleging false claims in connection with the sale of medical devices to VA medical centers.

Conducting an internal investigation of international pharmaceutical and seed manufacturer into allegations that the company sold pharmaceutical products and seeds to embargoed countries.

Defense of a manufacturer of genetically engineered drugs against allegations that it had engaged in off-label promotion of certain growth hormone products.

Representation of an international pharmaceutical company in connection with a DOJ investigation and related *qui tam* actions involving alleged
violations of Anti-Kickback Act, False Claims Act and Prescription Drug Marketing Act.

Defense of health care providers in connection with allegations of improprieties with respect to clinical research projects, billing and other issues.

Regulatory Counseling
We assist pharmaceutical, biotech, and medical device companies in a variety of regulatory matters in many forums. Representative engagements include:

Assisting clients in the drug and device approval process, complying with the incident reporting requirements, and negotiating restrictions on marketing before the Food and Drug Administration.

Counseling on a variety of regulatory and litigation related issues arising out of the framework of the Japanese Pharmaceutical Affairs Law and counsel on ongoing distributorship relationships in Japan.

Conducting benefit and risk analyses for products in development, to be used by company management as part of their marketing, advertising and labeling initiatives.

Filing comments on behalf of our clients on proposed regulations, guidance documents, and other regulatory initiatives affecting firms in the health care industry.

Counseling on risk management and risk assessment procedure before the launch of new products.

Assisting in legislative advocacy efforts before Congress and state legislatures, and framing business implications of new or proposed legislation.

Assisting in-house personnel and counsel in crafting advertising claims for media, print and direct mail consistent with legal requirements pursuant to federal regulations, the Lanham Act, state regulations and other industry guides such as those issued by the Council of Better Business Bureaus or the major television networks.

Evaluating substantiation for advertising claims including efficacy studies, consumer perception surveys and technical data.
Working with marketing experts to prepare efficacy studies and consumer perception surveys.

Representing clients before the Federal Trade Commission, Food & Drug Administration, state agencies, the National Advertising Division of the Better Business Bureaus or the major television networks.

We also have extensive experience counseling clients on the patient privacy and security rules issued by the Department of Health and Human Services under HIPAA. Although generally not treated as "covered entities" under HIPAA, firms in the pharmaceutical, medical device, and biotech industries need to be concerned about the numerous circumstances in which they collect or receive protected health information from physicians, hospitals, health plans, and other covered entities that may require them to enter into business associate or limited data use agreements or to assist covered entities in gaining waivers from institutional review boards. For instance, HIPAA will likely be implicated when companies sponsor clinical trials, organize patient outcomes databases, or send sales representatives into physician offices, hospitals, and other health care settings where they are exposed to patient data.

Transactional and Licensing

We represent businesses, including pharmaceutical companies, in their mergers and acquisitions, divestitures, securities offerings, financings, restructurings, joint ventures and numerous other types of matters. We have rendered services to a wide array of corporate clients, both domestic and international, including Fortune 100 companies and high-growth public companies. Our attorneys have broad and deep transactional and licensing experience. We have a strong array of talent to draw upon when counseling in, among other areas, corporate governance and SEC compliance and regulatory matters. We have represented pharmaceutical and life sciences companies in many transactional matters, including:

- Representation of a large multinational pharmaceutical company in connection with various licensing, patent, FDA collaboration and supply agreement related issues in the United States and internationally, including in respect of a joint venture.

- Representation of Cardinal Health, Inc. in its recent acquisition of Care Fusion, Inc., an industry leader in wireless, barcode-enabled patient identification systems used in hospitals.

- Representation of Honeywell International Inc. and a newly formed subsidiary, Honeywell HomMed LLC in the acquisition of HomMed LLC, a provider of home health care products and services.

- Representation of the life sciences division of a large Japanese company
in connection with forming a joint venture for research regarding the human proteome and commercialization of such research.

Representation of a large multinational pharmaceutical company in providing broad ranging corporate and other advice regarding a joint venture with another major pharmaceutical company.

Representation of a large pharmaceutical company in connection with a significant corporate transaction involving one of its joint ventures.

Representation of a medication management and medical supply solutions company on general corporate matters, including pre-IPO venture capital financing. The company went public and remains as an independent company.

Representation of Comprehensive Decubitus Therapy, Inc. (dba Advanced Tissue Management) in various ongoing corporate and transactional matters.

Representation of a large medical device company in connection with evaluating certain licenses for stent devices for use in medical treatments and formulating a strategy for renegotiating or sublicensing those licenses.

Representation of a biotech and pharmaceutical instrumentation company in connection with licenses for labeling and detection systems.

Representation (as co-counsel with Wachtell, Lipton, Rosen & Katz) of Cardinal Health, Inc. in its acquisition of Syncor International Corporation, a leader in nuclear pharmacy services.

Representation of a cancer drug development company in a series of financing and related transactions, including detailed familiarity with the company’s in-and out-licensing programs, as well as the drug testing and approval process. The company went public and was eventually sold to Genzyme.

Representation of a multinational corporation in the disposition of its pacemaker business to a publicly-traded medical device manufacturing company, with operations throughout the EU and South America.

Representation of private equity fund in its preferred stock investment in a privately-held company that develops and commercializes high content screening, informatics and cellular bioinformatics products for use by companies in the drug discovery market.
Representation of a large pharmaceutical company in the divestiture of various of its business units in the food ingredient and biotechnology industries. This representation included the negotiation of several license agreements and research and development agreements for chemicals and biotech materials.

Representation of a large chemical company in connection with evaluating certain of its licenses for chemical agents for use in medical treatments and formulating a strategy for re-negotiating such licenses.

Representation of a molecular electronics company in connection with licensing core intellectual property rights from several prominent universities, which licenses included equity investments by several of the universities involved.

Represented a large not-for-profit organization in the medical industry in connection with its licensing and supply agreements with a major medical supply company.

Representation of Dynacare, Inc., a provider of clinical laboratory testing services, in its sale to Laboratory Corporation of America Holdings in an approximately $450 million merger transaction.

Representation of a financial sponsor in connection with forming a company and related fund to make investments in late-stage healthcare companies and products.

Representation of Sterling Capital Partners in its acquisition of Ameritox Ltd.

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