Serving the Life Sciences Industry

King & Spalding
Bench Strength at Every Stage of the Product Life Cycle

King & Spalding’s life sciences practice is one of the largest and most comprehensive among law firms. More than 300 lawyers and professionals in 11 practice groups located in nine offices devote all or a substantial portion of their practices to clients in every segment of the industry. The firm currently represents more than 200 pharmaceutical, biotechnology and medical device manufacturers overall, including eight of the top 10 pharmaceutical/biotechnology manufacturers and eight of the top 10 medical device manufacturers.

We offer pharmaceutical, biotechnology and medical technology companies specialized experience at every stage of the product life cycle — from emerging growth company counseling on intellectual property, capital-raising transactions, license and corporate partnering agreements, and clinical trials, through FDA approval, manufacturing, marketing, commercial and post-approval regulatory, strategic M&A, and other corporate transactions, to litigation and government and internal investigation matters. Our government affairs lawyers also help our clients in the industry understand and navigate legislative and regulatory developments in Washington, D.C., and in state capitals across the country. And the firm continues to expand its international life sciences capabilities, with increasing numbers of dedicated practitioners in our international offices giving the firm the ability to represent our clients in cross-border transactions around the world.

From start-up through product launch to patent expiry, our clients rely on King & Spalding’s substantive expertise, bench strength and collaborative approach to client service.
360° Representation

At King & Spalding, we recognize that our clients are committed to protecting and promoting their businesses every day; as their legal partners, this is our commitment too. Our lawyers work together across all practice groups — one area of expertise informing another — to provide our clients with cost-effective, informed and strategic counsel based on thorough knowledge of the pharmaceutical, biotechnology and medical device industries and governing laws. This internal coordination is essential to helping our clients identify and consider future risks and preserve strategic options across the full spectrum of their business activities. As one client noted, “Cases can spill over into other things like regulatory issues . . . King & Spalding can bring it all.”

Chambers USA and The Legal 500 consistently rank King & Spalding’s life sciences team among the best in the United States.
Our lawyers share industry developments with our clients through the King & Spalding Pharmaceutical University and the Medical Device Summit.
Investing in the Life Sciences Industry

Over the past decade, King & Spalding has demonstrated its commitment to the life sciences industry by investing in people and tools to better serve our pharmaceutical, biotechnology and medical technology clients, including by:

Developing, cultivating and reinforcing bench strength in every key area of legal need, including emerging growth companies, intellectual property, capital-raising transactions, corporate partnering and collaboration agreements, commercial contracting, business and product liability litigation, government investigations, FDA and government payor regulation, strategic M&A and other corporate transactions, and government advocacy and public policy.

Deploying internal knowledge management systems focused on FDA-regulated manufacturers, ensuring that our lawyers and professionals stay informed about key industry and business developments.

Leveraging the expertise of nonlawyer professionals (including more than 30 MDs, PhDs and others with advanced medical, scientific and technical degrees) to provide counsel and support that integrates legal, regulatory, scientific and technical expertise.

Offering aggressive training programs both to internal lawyers and to clients focused on legal, regulatory and business developments of interest to pharmaceutical, biotechnology and medical technology companies.

Publishing the essential guide to pharmaceutical law, *Regulation of Pharmaceutical Manufacturers* (Law Journal Press, 2010), which includes comprehensive chapters devoted to the FDA, controlled substances, intellectual property, antitrust, insurance coverage, direct patent liability and successor liability, federal and state enforcement activity, whistle-blower claims, product liability, third-party payor litigation, securities litigation, and pharmaceutical class actions.

Sharing important industry developments with our clients through frequent webinars and electronic alerts, as well as substantive programs such as the King & Spalding Pharmaceutical University and the King & Spalding Medical Device Summit, which address the latest legal, legislative and regulatory developments affecting the industry.

These investments and our integrated approach have permitted us to represent our clients in the industry on a more cost-effective basis with respect to a broader array of legal issues.
Our Specialized Practices

Antitrust
Recognized by Chambers USA as “a sharp, practical, business-oriented group” that provides “a great mix of theory and practicality,” and singled out as a leader by Global Competition Review and The Legal 500, King & Spalding’s antitrust practice provides customized and solution-oriented advice to pharmaceutical, biotechnology and medical technology companies on all aspects of antitrust law, from civil and criminal litigation (including antitrust counterclaims in patent litigation) to advising on and obtaining approvals for mergers, acquisitions and joint ventures. We advise on the antitrust issues arising from patent settlements; assist clients on notification with the U.S. Department of Justice and the Federal Trade Commission pursuant to the Medicare Modernization Act; and appear regularly before key competition authorities, including the DOJ, the FTC, state attorneys general and the European Commission. We also provide proactive counseling and leverage our extensive industry experience to reduce risk and legal costs, using our “database” of precedent to avoid reinventing the wheel. We also help our clients stay on top of compliance with antitrust laws and take corrective action if necessary to avoid high-cost antitrust investigations and litigation. This work ranges from designing new or reviewing existing compliance programs and policies to conducting audits to ensure that these programs are working.

Appellate
Named a leading national practice by both Chambers USA and The Legal 500, King & Spalding’s national appellate practice group is headed by a former principal deputy in the Office of the Solicitor General, along with a former acting assistant attorney general for the Civil Division of the U.S. Department of Justice and an administrative law specialist recently recognized by Law360 as a “rising star” in the appellate arena. The partners in our national appellate practice have all been “recommended” by The Legal 500 and described as “extremely talented and creative lawyers.” The group has extensive expertise handling important appellate and administrative law matters for major clients in courts across the country. We often represent clients in administrative law cases before the D.C. Circuit. We frequently advise on litigation matters involving state regulatory agencies. And we have specific expertise handling litigation for clients in FDA-related regulatory matters. For example, we recently represented a global pharmaceutical and medical device manufacturer in a declaratory judgment action challenging FDA regulations that prohibit truthful, nonmisleading speech about off-label uses of FDA-approved prescription drugs. We also achieved a landmark decision rejecting the FDA’s assertion of new authority to regulate traditional pharmacy compounding practices. And we have deep experience handling major federal False Claims Act litigation on behalf of our pharmaceutical and healthcare clients.

Business Litigation
King & Spalding litigators have extensive experience representing life sciences companies in the kinds of cases that they regularly face, including the litigation and arbitration of licensing agreements and collaboration/joint-development agreements, supply and distributions agreements, acquisition agreements and post-closing disputes, qui tam litigation, trade secret litigation and securities class action litigation. Our lawyers have successfully represented life sciences clients in virtually every litigation forum, from federal and state trial and appellate courts to the U.S. Supreme Court, national and international arbitration panels, government agencies and alternative dispute resolution tribunals. We try high-profile cases on a regular basis, representing clients in matters ranging from class actions to multidistrict litigation, from complex business matters to small disputes and individual cases, and from arbitrations and mediations to negotiations and investigations. The American Lawyer recently ranked the firm among the 25 “most decorated law firms” in its inaugural Litigation Power Rankings.

Chambers USA ranks 48 lawyers from our life sciences practice among the nation’s best.
Corporate/M&A
Our corporate practice advises pharmaceutical, biotechnology and medical technology clients at all stages of their development and in connection with a wide variety of strategic corporate transactions, including venture capital and other financings, mergers and acquisitions, product acquisitions and dispositions, license and collaboration agreements, research and development agreements, co-promotion agreements, and supply and distribution arrangements. We also advise life sciences clients as well as private equity and venture capital firms in connection with strategic equity and venture capital investments in emerging growth companies and larger businesses. The firm has more than 150 corporate/M&A lawyers located in Atlanta, Charlotte, Dubai, Frankfurt, Houston, London, Moscow, New York, Silicon Valley and Washington, D.C. Our M&A practice is consistently ranked among the leading practices in the United States, and King & Spalding has been recognized as a leading law firm for corporate and M&A work by both The Legal 500 and Chambers USA. Mergermarket has also ranked King & Spalding among the top 10 law firms by deal volume for U.S.-based biotechnology M&A transactions. Chambers USA ranks 18 of our M&A partners who serve life sciences clients among the nation’s best.

Discovery Center
For more than 20 years, King & Spalding has been at the forefront of developing high-quality, cost-effective solutions to the challenges of collecting, reviewing and producing documents in complex litigation. As a primary part of these efforts, the firm created the Discovery Center in 1995 at the request of a client. The Discovery Center has been in continuous operation ever since, serving more than 160 companies, including some of the largest in the world. Today, the Discovery Center houses 250 experienced team members dedicated solely to discovery, due diligence and other document-related matters in an off-site facility designed from the ground up as the optimal environment for discovery work, with industry-leading resources, technology and proven protocols.

FDA & Life Sciences
Our FDA and life sciences practice is ranked by Chambers USA and U.S. News & World Report among the nation’s best for medical device, pharmaceutical and biotechnology regulatory work. With more than 30 lawyers and professionals in Washington, D.C., and Northern California, we provide sophisticated counseling to more than 150 drug and device manufacturers. Our integrated team includes attorneys with expertise in all areas of federal and state regulation of the life sciences industry, from product development, clinical testing, approval and manufacture through commercialization and payment. We regularly advise manufacturers with regard to complex matters of FDA, CMS, OIG and related agency compliance and litigation. Nine members of the practice have previously served in the FDA, including in the Office of Chief Counsel, the Office of Drug Policy, CDRH’s Office of Compliance and the Office of Device Evaluation, and as medical, regulatory and quality systems experts. Our team prides itself on providing thoughtful, creative, business-savvy and, above all, legally sound solutions for our life sciences clients.
“[King & Spalding’s healthcare team] is highly praised by both peers and clients for the breadth of its regulatory, litigation and transactional capabilities.”
— Chambers USA
Government Advocacy & Public Policy
King & Spalding’s government advocacy and public policy team leverages decades of experience and bipartisan relationships to develop and implement client strategies to maximize opportunity, minimize risk and accomplish strategic goals. In addition to providing direct advocacy before Congress and executive agencies, we assist clients in effectively responding to congressional inquiries, an area in which Chambers USA has noted that the firm “is particularly prominent.” Our team includes a former governor and member of the House of Representatives; a former U.S. chief of protocol; a former general counsel of the House of Representatives and chief of staff to the speaker of the House; a former staff director and general counsel of the House Rules Committee; a former staff director of the Senate’s Permanent Subcommittee on Investigations; a former staff director of the joint congressional inquiry on the terrorist attacks of September 11, 2001; and a former senior investigative counsel to the Senate Committee on Finance. Chambers USA ranks our government relations practice among the nation’s best, listing more individuals than any other law firm in the category and observing, “The team is notably strong in the healthcare sector.” In 2012, King & Spalding debuted at No. 12 on the National Law Journal’s annual survey of the 50 highest-grossing lobbying practices in the United States and was chosen by U.S. News & World Report and Best Lawyers as the “Law Firm of the Year” for government relations.

Healthcare
King & Spalding’s healthcare practice represents healthcare companies involved in the delivery of healthcare and payment for healthcare services across all facets of legal issues those companies face. We serve the entire spectrum of institutional providers, practitioners, payors, educators, researchers, inventors, suppliers, investors and manufacturers. King & Spalding was a finalist nationally for the Chambers USA Award for Excellence in healthcare in both 2011 and 2012. Our lawyers, scientists, policy analysts and consultants hold or have held leadership positions in the industry and in the U.S. government. We count among our lawyers three past presidents and a current director of the American Health Lawyers Association and a director and executive committee member of the Health Care Compliance Association. The American Health Lawyers Association has ranked King & Spalding’s health law practice the largest in the United States, with more than 240 health industry practitioners, for six consecutive years. Chambers USA has ranked 37 of our healthcare lawyers among the nation’s best; The Guide to the Leading U.S. Healthcare Lawyers includes eight members of our healthcare group; and Nightingale’s Healthcare News has recognized 18 of our lawyers as being among the top practitioners in the U.S.

Insurance Coverage and Risk Management
King & Spalding’s insurance coverage and recovery practice provides policyholders with the full range of insurance-related legal services, from the earliest phases of policy analysis and claim preparation to mediation and, as necessary, litigation, arbitration, trial and appeal across all industry sectors, including life sciences. Since 2002, we have recovered billions of dollars for policyholder clients in prelitigation settlements, arbitrations, mediations, and trial and appellate court judgments. In addition to providing insurance counseling and claim assistance, we serve as trial counsel to corporate policyholders in a variety of complex coverage cases involving numerous types of insurance coverages. We have extensive experience representing manufacturers in general liability claims, and our team’s reputation and credibility as trial lawyers who will aggressively pursue claims through trial increase our clients’ opportunities for early settlement. We work with our clients’ brokers and forensic accountants to evaluate and prepare property damage and business interruption claims in order to maximize available coverage. Our team also counsels business policyholders and assists risk managers in evaluating upcoming renewals of coverages and in comparing proposals from competing markets. In addition, we advise policyholders on complex insurance allocation and liability issues in mergers, acquisitions and other related transactions.
Intellectual Property
The success of companies in the life sciences industry often hinges on their ability to protect, enforce, defend against or acquire intellectual property rights (particularly patent rights) relating to the drugs, medical devices or diagnostic tests at the core of their business. King & Spalding’s lawyers, patent agents and scientific advisors, many with PhDs or other advanced degrees in relevant scientific disciplines, understand both the law and the technology, allowing them to provide clients with world-class counseling and representation in all areas of intellectual property law relevant to the clients’ businesses. In IP Law & Business magazine’s annual survey of the country’s top 50 most innovative companies, King & Spalding was recognized as one of the law firms most frequently mentioned as legal counsel on intellectual property matters. Our lawyers and other professionals work with clients throughout the entire life cycle of intellectual property rights, from consulting with inventors and in-house counsel in order to prepare, strategize and prosecute patent applications that protect the client’s inventions to handling complex litigation in order to enforce the client’s patent rights or defend against those being asserted by others. Our broad litigation expertise includes both ANDA and biologics litigation at the district court and appellate levels, with our lawyers having litigated some of the most important cases in the industry. We also represent clients in a wide variety of transactions involving the transfer of intellectual property rights valued at billions of dollars.

International Arbitration
Winner of a Chambers USA Award for Excellence and recognized by Focus Europe, The Global Arbitration Review and Chambers Global as one of the best in the world, our international arbitration practice offers our pharmaceutical, biotechnology and medical device clients a full range of advice concerning the protections and remedies afforded by commercial agreements and international treaties. Where appropriate, we assemble the best team of advocates and subject matter experts to pursue or defend claims related to intellectual property disputes, international licensing and distribution arrangements and cross-border investments. Our lawyers have been involved in arbitrations and arbitration-related litigation involving parties or projects across six continents, and they have handled arbitrations under the rules of every major arbitral institution as well as under ad hoc rules. With a multicultural group of international lawyers trained in both common law and civil law systems and fluent in more than 12 languages, we are able to handle cases effectively and efficiently anywhere in the world.

Labor & Employment
King & Spalding was identified as a “go-to” law firm for labor and employment on Corporate Counsel’s “Go-To Law Firm” list and has been recognized by Chambers USA for its “excellent service and impressively high success rate.” Our partners have represented clients in the pharmaceutical and biotechnology industries for decades, including in state and federal court litigation involving equal employment opportunity laws, whistle-blower retaliation claims, restrictive covenants, trade secrets, wage and hour disputes, and compensation and benefits issues. On the counseling side, our service to employers ranges from preventive advice and training to formulating and implementing diversity programs and affirmative action plans. Collectively, our employment litigators have tried hundreds of jury cases and arbitrations and defended dozens of class and collective actions. U.S. News & World Report recently quoted a pharmaceutical client as describing one of our partners as “one of the best, most experienced employment trial lawyers in the country. His excellent skills coupled with the laudable support always provided by his colleagues makes him and King & Spalding an especially attractive firm in any matter, but especially high-stakes litigation.”

LMG Life Sciences, which recognizes the “highest profile, most sought-after and best-attorneys working in life sciences,” recommends King & Spalding in the areas of FDA-medical device regulatory work, government investigations/fraud & abuse and product liability matters.
Product Liability/Mass Tort
With 37 partners and nearly 300 additional lawyers, our national product liability practice is consistently recognized as one of the best in the nation by Law360 (“Product Liability Group of the Year”), The American Lawyer (one of the top three product liability practices in the U.S.), Benchmark (“Product Liability Firm of the Year”), U.S. News & World Report (mass tort tier one), The Legal 500, The National Law Journal and Chambers USA, each of which noted our achievements on behalf of clients in the pharmaceutical industry. Clients tell us that several characteristics differentiate us from other firms: First, we have a deep bench of lead trial lawyers who try cases every year. We have five Fellows in the American College of Trial Lawyers, including its president. In fact, we are one of very few firms in the country to have tried class action lawsuits to verdict. Second, as a result of our ability and willingness to go to trial, we bring a strategic focus that is often missing in litigation. This includes expertise in identifying and preparing medical and scientific expert witnesses, as well as strategically attacking plaintiffs’ experts on Daubert grounds, and in working closely with our off-site Discovery Center to provide state-of-the-art litigation support capabilities that alleviate the burden of e-discovery. And finally, we take ownership of the client’s problem as our own, and we understand the business context. We serve as lead counsel in literally hundreds of cases filed in all 50 states, and our clients feel comfortable putting King & Spalding lawyers forward as the face of their companies. Indeed, The American Lawyer described King & Spalding’s product liability practice as “one that companies call on to handle the most delicate matters and navigate the toughest jurisdictions.”

Special Matters/Government Investigations
Our government investigations practice has been recognized as “White Collar Practice Group of the Year” by Law360, has been described by clients in the annual U.S. News & World Report/Best Lawyers Survey as “outstanding” and a practice that “consistently delivers superb legal services,” and was profiled by The Legal 500 as having “all-encompassing expertise ... across a broad swathe of white-collar matters.” Our members include more than 50 lawyers in five offices dedicated full time to criminal and civil investigations and related pharmaceutical litigation, including the former DOJ assistant attorney general in charge of the Criminal Division; more than a dozen former federal prosecutors, congressional investigators and other enforcement officials; and lawyers who have devoted their entire careers to white-collar criminal defense, congressional investigations and related civil and qui tam litigation. These lawyers have decades of collective experience in representing healthcare, pharmacy, PBM, pharmaceutical, biotechnology and medical device companies in every phase of government investigations and administrative matters, including those convened by state, federal and congressional entities, including the DEA, DOJ, FDA, FTC, HHS-OIG, SEC, state attorneys general, MFCUs, state Medicaid Integrity Programs and many others.

We regularly handle investigations of all types in the life sciences field, such as matters regarding alleged “off-label” promotion; unlawful inducements; and other sales, marketing, clinical and development activities in jurisdictions throughout the U.S. Our expertise extends to international and global investigations as well, and we have conducted Foreign Corrupt Practices Act investigations in many countries throughout the world. Our individual lawyers include Fellows of the American College of Trial Lawyers and have been singled out by Chambers USA, The Best Lawyers in America, Law360 and The Legal 500 as being among the nation’s best.
Practice Highlights

More than 300 King & Spalding lawyers and nonlawyer professionals devote all or a substantial portion of their time to servicing life sciences companies.

We represent more than 200 pharmaceutical, biotechnology and medical device manufacturers on litigation, intellectual property, regulatory and corporate matters, including eight of the top 10, 15 of the top 20, and 18 of the top 25 pharmaceutical/biotechnology manufacturers, as well as eight of the top 10 and 12 of the top 20 medical device manufacturers.

Eleven King & Spalding lawyers were identified as “life sciences stars” in the first-ever edition of LMG Life Sciences, which recognizes the “highest profile, most sought-after and best-attorneys working in life sciences.” In addition, the firm was recommended in the areas of FDA/medical device regulatory work, government investigations/fraud and abuse, and product liability matters on behalf of life sciences clients.

Our life sciences clients range from large multinational businesses to early-stage companies. Approximately 50 of our current pharmaceutical and medical device clients are early-stage R&D companies.

King & Spalding’s team of pharmaceutical-focused litigators includes seven members of the American College of Trial Lawyers, including the current president; the former assistant attorney general in charge of the Criminal Division; the former acting assistant attorney general of the Civil Division; a former deputy assistant attorney general with responsibility for the Office of Consumer Litigation; a former associate deputy attorney general with responsibility for domestic and international drug enforcement and drug policy; more than a dozen former U.S. attorneys, assistant U.S. attorneys and other DOJ trial attorneys; two members of the American College of Employment Lawyers; and the former chairman of the 10,000-member Food and Drug Law Institute.

Four of the firm’s top 25 clients are FDA-regulated pharmaceutical and medical device companies.

We leverage the expertise of nonlawyer professionals (including more than 30 MDs, PhDs and others with advanced medical, scientific and technical degrees) to provide counsel and support that integrates legal, regulatory, scientific and technical expertise.

Chambers USA and The Legal 500 consistently rank King & Spalding’s life sciences team among the best in the United States. Chambers USA has ranked 48 lawyers from our pharmaceutical, biotechnology and medical device industry practice among the nation’s best.

According to a survey by Modern Healthcare magazine, we have the largest health law practice in the nation, providing additional depth of experience on healthcare regulatory and litigation issues.
King & Spalding’s life sciences practice “is increasingly perceived as a viable destination for important litigation and a practice that ‘can be relied upon to handle very significant matters.’ ‘Excellent judgment’ and a ‘proactive and pragmatic’ demeanor are among the qualities that appeal to clients, who also highlight the group’s ‘good value’ as another plus.”
— The Legal 500

“King & Spalding has a well-earned reputation defending pharmaceutical companies in major government investigations. They understand the business, the issues, the opposition, and provide unique insight on how best to resolve these investigations.”
— Senior counsel at a multinational pharmaceutical company

“This widely acclaimed group maintains its position as a leading force in the market, and offers expertise across the board. Its strength in Medicare and Medicaid matters is highlighted along with its transactional expertise and experience in government investigations.”
— Chambers USA

“The firm has excellent connections to the government and is very well respected and trusted by regulators, the DOJ and the OIG, which is essential when negotiating with governmental authorities.”
— Senior vice president and general counsel at a top 20 pharmaceutical company

“The firm’s life sciences litigators are ‘terrific — first-rate lawyers, closely aligned with the client’s objectives; dedicated, responsive, and able to work with a whole lot of moving pieces and to see the big picture.’”
— The Legal 500

“King & Spalding is a huge reservoir of legal talent for FDA issues.”
— CEO and president of a biotechnology company

“They provide top-notch legal work, no doubt about it. They leave no stone unturned and uncover all of the issues.”
— King & Spalding client quoted in Chambers USA

“King & Spalding has exceptional talent and delivers consistently high quality results. They are the undisputed leaders in the medical device regulatory sphere, and their drugs/biologics and other FDA regulatory practice areas are also top-notch. They are the best I’ve seen at conducting highly professional and timely privileged investigations and audits.”
— Vice president, FDA/regulatory law, of a multinational biopharmaceutical company

“Clients value [King & Spalding] lawyers for their ‘knowledge of the courts and juries, and ability to get things done.”
— The Legal 500
Representative Matters

King & Spalding lawyers work together across practice groups to serve clients’ comprehensive business and legal needs. The following matters highlight our interdisciplinary approach to client service while representing only a small portion of our expertise.

King & Spalding represented Allergan, Inc., in connection with a Department of Justice investigation of the company’s sales and marketing of Botox®. King & Spalding lawyers from the special matters, business litigation and FDA & life sciences groups led the company’s defense and negotiated a global resolution of the DOJ’s criminal investigation, civil claims under the False Claims Act and related whistle-blower actions filed in federal district court. Lawyers in the appellate litigation group also represented Allergan in a declaratory judgment action filed in federal court in Washington, D.C., against the government, challenging FDA regulations that prohibit truthful, nonmisleading speech about off-label uses of FDA-approved prescription drugs. Allergan’s declaratory action was the first serious challenge in more than a decade to the government’s enforcement position criminalizing such speech.

We represented Boehringer Ingelheim Pharmaceuticals, Inc., in connection with an investigation by the Department of Justice and the U.S. Attorney’s Office in Maryland of the company’s sales and marketing of Aggrenox®, Atrovent®, Combivent® and Micardis®. King & Spalding lawyers and consultants from the special matters and FDA & life sciences groups led the company’s defense and negotiated a global resolution with federal and state regulators from the 50 states and the District of Columbia, which included handling the company’s Corporate Integrity Agreement with the inspector general of the U.S. Department of Health and Human Services. The civil-only settlement resolved civil claims under the False Claims Act and the Anti-Kickback Statute and a related whistle-blower action filed in federal district court.

King & Spalding successfully defended Japanese pharmaceutical company Eisai in an investigation conducted by the Boston U.S. Attorney’s Office into Eisai’s sales and marketing practices, including alleged off-label promotion, for its medication Zonegran®. After a four-year investigation, King & Spalding resolved the matter with the U.S. Attorney’s Office and dozens of state attorneys general for $11 million on a “civil only” basis, an unusual and favorable result relative to other cases resolved in that district. We likewise represented Eisai in a civil investigation by the Philadelphia U.S. Attorney’s Office into certain AMP reporting matters, which resulted in a government decision to decline to intervene in an unsealed qui tam complaint and, after the relator pursued the litigation, a full dismissal after the district court considered our motion to dismiss pleadings and oral argument.

King & Spalding obtained a significant victory for Franck’s Lab, Inc., in a district court ruling rejecting the U.S. Food and Drug Administration’s request for an injunction that would have shut down almost half of Franck’s business and prevented the company from engaging in the traditional, state-regulated practice of compounding animal medications from bulk ingredients. This landmark ruling is important for hundreds of compounding pharmacies across the U.S. and, because it recognizes limits on the FDA’s ability to take enforcement actions based on informal, nonbinding guidance documents, has significant ramifications for all FDA-regulated industries.
For nearly a decade, we have served as lead national counsel to GlaxoSmithKline (GSK) in litigation and related matters involving the antidepressant Paxil®, including defending the company in multidistrict proceedings pending in California and Pennsylvania and individual suits throughout the country and responding to government investigations at the state and national levels. In the past two years alone, our team has won a “bellwether” product liability trial and successfully obtained numerous summary judgments and appellate victories. We have provided comprehensive legal services to GSK by utilizing a broad team of lawyers that spans many practice areas, including product liability, commercial disputes, FDA & life sciences, government advocacy and congressional investigations. Attorneys in every one of King & Spalding’s U.S. offices have played significant roles in representing GSK.

In addition to our work related to Paxil®, we advise GSK on FDA matters, defend GSK in commercial litigation and employment discrimination cases, and provide counsel on corporate transactions.

We also represented GSK in connection with its acquisition of the worldwide rights to Toctino®, a product for the treatment of severe hand eczema, from Basilea S.A., a Swiss company. Our M&A lawyers in Atlanta and London worked with GSK on the transfer to GSK of the Toctino® product rights, the licensing to GSK of the intellectual property rights of Basilea related to Toctino® and the transfer to GSK of the marketing approvals for Toctino® in a number of countries. Our labor and employment lawyers advised GSK on the transfer to GSK of the employees of Basilea who devoted substantially all their time at Basilea to the development and commercialization of Toctino®. Lawyers from our IP and FDA/regulatory practice groups assisted us in negotiating the terms of the transaction agreements related to their specialties.

King & Spalding serves as national coordinating counsel for Janssen Pharmaceuticals, Inc., a subsidiary of Johnson & Johnson, in cases alleging fraud in prices it reported for prescription drugs. Attorneys general for various states and a proposed class of third-party payors claim that Roche reported “inflated” WACs and/or AWPs for its drugs because the prices were not actual averages and did not reflect discounts. King & Spalding successfully moved to have Roche dismissed from a national class action in the related multidistrict litigation.

King & Spalding advised Immucor, Inc., a provider of automated instrument-reagent systems to the blood transfusion industry, on its $1.94 billion sale to IVD Acquisition Corporation, an affiliate of TPG Capital. The transaction, which provided Immucor shareholders a significant premium over the pre-closing share price, positions Immucor to develop new products and pursue global expansion.

We represented Janssen Pharmaceuticals, Inc., a subsidiary of Johnson & Johnson, in a high-profile investigation conducted by the Department of Justice, the U.S. Attorney’s Office in Boston and various other state attorneys general into the company’s sales and marketing practices of one of its pharmaceutical products, Topamax®. We successfully negotiated a global settlement with federal and state regulators, which included handling the company’s Corporate Integrity Agreement with the inspector general of the U.S. Department of Health and Human Services while federal sunshine legislation became effective. We also successfully negotiated Medicaid claims by the 50 states and the District of Columbia. We resolved the matter globally in 2010 for approximately $81.5 million, which extinguished the company’s criminal liability and civil False Claims Act exposure and allowed the company to continue participating in federal programs. We also represent the company in similar investigations and litigation related to the sale and marketing of the atypical antipsychotic drugs Risperdal® and Invega®. We successfully negotiated a settlement with the attorneys general of 37 states that conclusively resolved the company’s liability under state consumer protection laws. We continue to represent the company in related state and federal investigations. These matters combine the expertise of our special matters/government investigations, FDA & life sciences, business and appellate litigation, and government advocacy & public policy practice groups to provide comprehensive counseling and strategic direction through one interactive team.
King & Spalding successfully represented McKesson Technologies Inc. in the Federal Circuit. Our lawyers persuaded the court to grant en banc review of the question whether a method patent can be evaded by dividing the patented steps among more than one entity, a frequently recurring and vitally important question for many of our clients. A closely divided en banc court ruled in our favor, holding that if a defendant induces two or more entities to combine to perform a patented method collectively, it can be held liable for induced infringement.

We represent Merck in litigation involving its osteoporosis medication Fosamax®. King & Spalding is co-lead counsel in the multidistrict litigation in the District of New Jersey and is trial counsel in the multidistrict litigation in the Southern District of New York. We recently obtained a defense verdict for Merck against a plaintiff’s claim that Fosamax® caused her to develop osteonecrosis of the jaw. The September 2011 trial was the fourth “bellwether” trial in the Fosamax® MDL in the Southern District of New York and was particularly significant for Merck in the overall MDL because this plaintiff was selected as the lead plaintiff in a putative class action by the MDL Plaintiffs’ Steering Committee. Since 2010, King & Spalding has represented Merck against claims that Fosamax® causes atypical femur fractures. We serve as co-lead trial counsel in the Fosamax® MDL in the District of New Jersey and are responsible for preparing numerous cases for early trial. Before becoming involved in Fosamax® matters, we served as national coordinating counsel for litigation involving claims that Singular® causes suicidal thoughts and behavior, helping Merck develop its defense strategy and prepare for litigation. Despite numerous claims, only one lawsuit was ultimately filed. We were able to demonstrate a readiness and willingness to aggressively litigate the case that ultimately led the plaintiff to dismiss the lawsuit during the discovery phase of the case. In addition to our product liability work, lawyers from the firm’s intellectual property group have been successfully representing Merck in a number of Hatch-Waxman cases.

King & Spalding represented Purdue Pharma in connection with congressional investigations into the abuse and diversion of the company’s pain medication, OxyContin®. Lawyers and consultants in our government advocacy, special matters, products liability and FDA & life sciences groups represented Purdue in connection with the investigations and hearings conducted by five separate congressional committees, as well as a two-year investigation by the Government Accountability Office, which culminated in a December 2003 report. In addition, lawyers in our products liability group have served as national coordinating co-counsel and lead trial counsel to Purdue Pharma in litigation involving OxyContin® and related civil and criminal investigations. Our lawyers have obtained 407 dismissals, including more than 30 orders granting summary judgment, and have defeated 16 putative class actions. Most recently, we obtained the dismissal of a putative nationwide class action filed by a consumer in California under the state’s consumer protection acts, in which plaintiffs sought hundreds of millions of dollars in restitution and other economic damages allegedly incurred by consumers who purchased OxyContin® during the class period. The firm also serves as liaison for Purdue’s coordinated defense with Abbott, which co-promoted OxyContin®.
We represented **UCB Pharma, Inc.**, in the formation of a worldwide alliance that gave Shire Pharmaceuticals the right to promote and commercialize the use of Equasym™ outside the United States and Canada. Our M&A/corporate lawyers worked with UCB on the transfer of UCB’s Equasym™ product rights and related intellectual property rights to Shire. Our M&A/corporate lawyers also advised UCB on the supply arrangements between UCB and Shire for Equasym™. Our IP lawyers advised UCB on the terms of the license from UCB to Shire of UCB’s patent, trademark and know-how rights related to Equasym™. Our corporate lawyers also advised UCB on the formation of a worldwide alliance that gave Shire the right to promote a branded pharmaceutical in an international arbitration under the World Intellectual Property Organization Rules. King & Spalding’s client licensed its rights to an established drug to a U.S.-based company. The licensee was required to conduct clinical trials and then seek approval from the U.S. FDA to use the drug for a new indication. The licensee failed to achieve FDA approval. The firm’s FDA & life sciences group led an investigation into the licensee’s conduct of the clinical trials to determine why they failed. Following that investigation, the case was settled on favorable terms.

The firm represented a **large biopharmaceutical company** in connection with the formation of a new subsidiary to perform all of the parent’s sales and marketing functions, including contracting, order management and rebate administration. Our M&A/corporate lawyers worked closely with the client to create the corporate foundation of the new subsidiary and advised on the asset transfers necessary to complete the reorganization. The asset transfers required that our lawyers, relying in part on the cost-effective resources of our Discovery Center, review and evaluate more than 10,000 customer contracts to provide guidance regarding assignment and novation. Our FDA & life sciences attorneys developed regulatory strategies to minimize the government pricing implications of the creation of the subsidiary, and our IP lawyers worked with the client to provide the new subsidiary with the intellectual property rights necessary for it to conduct the company’s sales operations.

We successfully represented a **major branded pharmaceutical company** in multiple patent litigations in Delaware, New Jersey and North Carolina federal district courts, including two Paragraph IV Hatch-Waxman challenges to a patented drug delivery system for an anesthetic agent and a lawsuit and corresponding reexamination proceedings relating to method patents for blood plasma screening. These patent litigation matters have involved substantial collaboration of our patent litigation, FDA/regulatory and antitrust teams. For example, King & Spalding advised the company on the development and prosecution of a citizen petition to the FDA to ensure that patent certification and regulatory stays appropriately postponed a competitor’s request for approval of a generic version of the company’s anesthetic agent. The FDA granted the petition in the company’s favor in a time frame notably faster than required by applicable procedural law.

A multidisciplinary team of King & Spalding’s FDA & life sciences, intellectual property, product liability and commercial litigation (e.g., Lanham Act) lawyers has undertaken a comprehensive risk assessment for a **pharmaceutical manufacturer** involving a new product currently under FDA review. Through an extensive series of site visits, personnel interviews, documentary reviews and other evaluations, we identified and prioritized compliance or other key risk issues (e.g., potential FDA review issues, potential product liability concerns) that accompany the product and then presented our findings. We offered concrete recommendations for short-, medium- and long-term actions to add or augment existing controls or to fill in any remaining gaps.

We represent a significant number of **development-stage life sciences companies** in matters such as intellectual property prosecution and strategy, capital-raising transactions, corporate partnering and license agreements and collaborations, commercial agreements, FDA counseling, and strategic transactions.

We have represented the venture capital units of **large pharmaceutical companies** in connection with strategic minority investments in product development companies, and we have assisted in negotiating investment terms as well as the investing company’s governance rights and rights to acquire or gain preferential access to developed products and related intellectual property.

We have represented several **public life sciences companies** in their strategic investments and partnering transactions. These transactions include inbound licenses and acquisitions of development programs, as well as strategic equity investments that are being made in tandem with a strategic arrangement or license.
Representative Clients

Adolor Corporation
Alfa Wasserman
Allegiance
Alpharma
Altiris Therapeutics
Amgen
Arbor Pharmaceuticals
Astellas
AstraZeneca
Baxter Healthcare
BD
BioMarin
Boehringer Ingelheim
Boston Scientific
Bristol-Myers Squibb
CVS Caremark
Cardinal Health
Care Capital
CareFusion
Celgene
Columbia University Technology Ventures
Corium International
Cumberland Pharmaceuticals
Daiichi Sankyo
Danco Laboratories
Defibtech
Depomed
Dornier MedTech
Dow Chemical
DRI Capital
Edwards Lifesciences
Eisai
Eli Lilly
EMD Serono
Emory University
Enzo Biochem
Fresenius Medical Care
GE Healthcare
Georgia Tech Research Corporation
GlaxoSmithKline
Hill-Rom
Immucor
Intuitive Surgical
Jazz Pharmaceuticals

Johnson & Johnson
Kinetic Concepts USA, Inc. (KCI)
Labcyte
Macro genes
McKesson
MedImmune
Medtronic
Merck
Merial
N30 Pharmaceuticals
NVS Technologies
Nektar Therapeutics
Novo Nordisk
Omnicare
Onyx Pharmaceuticals
PerkinElmer
PharmaMar
PsychoGenics
Purdue Pharma
Quidel
Regado Biosciences
Re Vance Therapeutics
Revivicor
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