SheppardMullin

# Life Sciences

Sheppard Mullin assists clients in the life sciences industry with strategic issues that range from acquisitions to antitrust, entity formation to enforcement and investigations, incorporations to IPOs, licensing to litigation, patents to product liability, and trademarks to transactions. In an industry where partnerships and collaborations are on the rise and there is pressure to produce results, we work hand-in-hand with our clients in their drive for success and profitability.

Our Life Sciences team is comprised of a cross-section of attorneys, patent agents, and scientific advisors whose particular strengths cover the legal needs of both emerging and established companies. Many of our team members have hands-on research experience and advanced degrees, including Ph.D.s in the areas of biochemistry, cell biology, chemistry, molecular biology, bioinformatics, pharmacology, and bio-medical engineering enabling us to fully understand our clients' business and objectives.

We represent a diverse client base in the biotechnology, pharmaceutical (prescription and OTC), medical devices and diagnostics, digital health and medtech sectors, ranging from large publicly-traded organizations to early and mid-stage start-up companies. Our attorneys in the US, and internationally through our offices in London, Brussels, Seoul and Shanghai, work with life sciences companies in a broad cross section of matters, including:

## Antitrust and Competition

Our Antitrust and Competition attorneys advise life sciences companies on antitrust strategies and defense, including mergers and acquisitions, joint ventures, alliance and conduct matters, licensing and patent settlements, and originator/generic competition. We also counsel clients on FTC MMA pharmaceutical agreement compliance, global transactions, Committee on Foreign Direct Investment in the U.S. (CFIUS), lifecycle management, R&D activities, co-marketing/co-promotion agreements, pricing/reimbursement issues, Hart-Scott-Rodino Act compliance, and import/export controls, sanctions and customs issues.

In addition to counseling and work relating to agency investigations, our experts advise clients on litigation in front of EU Courts, and also on private litigation in national courts, where an increasing amount of competition and regulatory disputes are being fought.

## Capital Markets and Strategic Alliances

**Formation**

The starting point for any life sciences business is the choice of the legal entity or entities within a structure in which to operate the enterprise. Sheppard Mullin has structured, organized and documented all types of legal entities in California, Delaware and other states and foreign countries, working with clients ranging from single, inexperienced entrepreneurs to veteran managers, venture capitalists and strategic investors, as well as domestic and international company owners.

**Capital Markets**

Sheppard Mullin has an active capital markets practice involving registered public offerings, including IPOs and follow-on offerings and private placements, including venture capital investments and other exempt transactions. We have served as counsel to a variety of issuers and investment banking firms in connection with public and private offerings of securities. The hands-on experience of our attorneys in a wide variety of offerings gives us the ability to develop creative solutions to problems encountered in the course of any securities transaction. Beyond the IPO, we also provide our life science clients with advice on the entire array of issues affecting public companies, particularly in areas such as corporate and securities laws, tax matters, mergers and acquisitions, intellectual property, litigation, antitrust and competition law, employee benefits, and environmental law.

**Joint Ventures and Strategic Alliances**

Sheppard Mullin has special expertise in structuring and negotiating joint ventures and strategic alliances (whether in corporate, limited liability company, partnership, contractual or other form of joint enterprise or through strategic contracts and licenses) for resource and product acquisition, distribution, development, infrastructure development, market penetration and risk sharing purposes, as well as all related ancillary agreements, such as marketing, distribution, license and supply agreements. While our corporate attorneys generally coordinate all aspects of joint venture and strategic alliance representation, through our Strategic Alliance practice they work closely with attorneys in other areas such as antitrust, government contracts and tax in order to provide broad support for these critical arrangements. Structuring and negotiating these very complicated transactions requires, in addition to legal guidance and counseling, substantial business experience; all of which we have garnered through the depth of our experience in these transactions.

## FDA Regulatory Compliance and Enforcement

Our attorneys represent companies across an array of industries—pharmaceutical, biologics, medical devices, digital health and medtech, dietary supplements, and cosmetics—on matters spanning the total product lifecycle, from concept to commercialization. We bring an innovative approach to resolving complex regulatory issues that complements our client's cutting-edge technologies and novel products.

Our work begins in the planning and research and development phases and includes counseling on strategies for product positioning, review of novel ingredients and technology, the conduct of clinical trials, and market and patent exclusivity options. As part of the product development and approval phase, we assist clients in the preparation and submission of marketing applications, help facilitate meetings with FDA and other international regulators, and assist in the preparation for pre-approval inspections. We also partner with clients to handle and resolve post-marketing issues, such as product safety issues, including adverse event reporting and recalls, import-export issues, obtaining supplemental approvals, responding to formal and informal agency enforcement actions, and all aspects of marketing, including, labeling, advertising and promotion issues. Our team also handles complicated legal and regulatory aspects of inspections and audits, including representing clients before the FDA and U.S. DOJ, conducting cGMP and QSR audits and data integrity reviews, and assisting clients in responding to agency enforcement actions, including 483s, Warning Letters, and investigations.

Our attorneys also have extensive experience in conducting regulatory compliance due diligence audits of potential acquisition targets and negotiating licensing, supply, and distribution agreements.

## Healthcare Regulatory and Compliance

Operating in the healthcare industry today means navigating a highly complex and constantly evolving array of federal, state, and local laws and regulations. We provide counsel to healthcare clients in virtually all manner of regulatory compliance and enforcement issues. We routinely advise on physician self-referral laws, fraud and abuse laws, corporate practice of medicine and fee-splitting prohibitions, CLIA compliance, HIPAA privacy, charitable trust law, private inurement, private benefit and excess benefit restrictions, antitrust, licensure, accreditation, Medicare and Medicaid reimbursement, certificate of need/certificate of exemption laws, and medical staff bylaws issues.

## Licensing, Clinical Trials, Collaboration and Development

Life sciences companies rely on strategic alliances with third parties for financing research and development, validating technology, expanding clinical candidate and product pipelines, commercializing products and penetrating domestic and global markets. Sheppard Mullin has special expertise in structuring and negotiating joint ventures and strategic alliances for resource and product acquisition, distribution, development, infrastructure development, market penetration and risk sharing purposes, as well as all related ancillary agreements, such as marketing, distribution, license and supply agreements.

Whether it is the acquisition or licensing of technology, the protection, development and capitalization of intellectual property assets, or the creation of a strategic partnership or joint venture, we have the experience, relationships, and resources available to bring value to our clients throughout the transaction. Our attorneys are highly skilled in the strategic planning of patent portfolios, including meshing the focus of the portfolio with competitive intelligence and a company's business plan.

We have substantial experience in drafting and negotiating global clinical trial agreements, Contract Research Organization (CRO) and laboratory agreements, manufacturing and supply agreements and the related work orders, budgets and forecasts. In negotiating these agreements, we have been successful in protecting our clients' interests, especially in resolving disputes without resorting to legal action.

Sheppard Mullin is equipped to address all types of transactions involving our life science clients:

- License Agreements
- Collaborations
- Clinical Trial Agreements
- Complex Manufacturing and Supply Deals
- Joint Ventures
- Distribution Agreements, including OEM, VAR, sales representative, etc.
- Technology and Materials Transfer Agreements
- Services Agreements and Outsourcing
- Confidentiality Agreements
- Employee and Contractor Intellectual Property Agreements
- Asset Sales

- Emerging Economy Transactions

## IP Litigation

Over the past 20 years, patent rights have assumed an even more critical role in business, particularly in the life sciences. The successful resolution of a patent dispute requires a unique blend of skill, understanding and experience in litigation, patent practice and technology. We draw on Sheppard Mullin's extraordinary depth of trial experience in staffing our IP cases, bringing in specific trial skill sets as needed to complement our technical and patent-specific litigation expertise.

Our IP attorneys have experience in all aspects of the laws governing patents, trademarks, trade secrets, know how, copyright, false advertising and other matters involving life science intellectual property. If early dispute resolution is not possible, we have trial attorneys with the experience to resolve matters in the courtroom. Our attorneys have litigated matters in federal courts, state courts, The American Arbitration Association (USA), The International Dispute Resolution Center (NY), The International Chamber of Commerce (Europe), and other international venues.

Sheppard Mullin's patent litigators have handled cases throughout the United States, including all of the district courts known for handling major patent cases—D. Del., E.D. Va, E.D. Tex., D. N.J., N.D. Ill, S.D.N.Y., D. Mass., C.D. Cal., N.D. Cal.—as well as the Supreme Court, the Federal Circuit, the U.S. International Trade Commission (ITC), and numerous other district courts. As a result, our attorneys have deep and broad expertise in all phases of patent litigation from pre-litigation counseling through Markman hearings, dispositive motions, jury trials, and appeals.

## Patent Strategies, Prosecution and Counseling

Life sciences companies seeking to expand, exploit or protect their patent portfolios routinely turn to Sheppard Mullin. With more than 50 registered patent attorneys with diverse technical backgrounds, Sheppard Mullin offers a complete patent practice, including patent prosecution, licensing and related transactional matters, as well as providing opinions of counsel, strategic audits and due diligence in connection with corporate transactions.

We assist companies, from small start-up ventures to global enterprises, in developing and implementing company-specific patent strategies, evaluating the patentability of new products and inventions, and preparing and prosecuting patent applications in the United States and throughout the world. Our patent practitioners handle the initial preparation and filing of the applications and the subsequent prosecution of the applications before patent examiners and before the USPTO's Board of Patent Appeals and Interferences. We have a support group of highly experienced administrative assistants to handle administrative tasks and post-issuance matters, including the preparation and recordation of assignments and the payment of maintenance fees and annuities. Our expertise with patent prosecution spans foreign countries all around the world.

We also render opinions concerning the validity, enforceability and infringement of patents. Our reviews for proper issuance, validity, and enforceable involves a carefully study of the patent, its claims and prosecution history (the written record of prosecution of the patent from filing to issuance) to determine whether or not the patent claims comply with the requirements for patentability, including novelty, non-obviousness and support by an enabling disclosure. In addition, we prepare product clearance opinions so that a company can have a reasonable comfort level that a new product does not infringe patents held by others.

## Privacy and Cybersecurity

We partner with clients in the life sciences, digital health, and medtech industries to help them extract value from the data they collect, while identifying and addressing regulatory compliance requirements, and ensuring that data is appropriately protected. Our attorneys have experience responding to high-profile data breaches, including state-sponsored attacks, and the regulatory investigations, Congressional oversight and litigation that often follow such incidents. We litigate major privacy and security related class actions. We provide strategic counsel to help companies understand emerging developments in this rapidly changing area of law, particularly with EU data collection and international data transfers including GDPR compliance. As data becomes more entwined with the enterprise value of businesses, we conduct data and privacy compliance due diligence in connection with mergers and acquisitions and other corporate and strategic transactions.

Our 30+ global, interdisciplinary Privacy & Cybersecurity Team includes some of the most respected attorneys in the privacy space, including an attorney who literally “wrote the book” on data breach, award-winning privacy class action litigation practitioners, and leading EU-based data protection experts. Many team members are CIPP-US and CIPP-EU certified by the IAPP, underscoring our commitment to the privacy field.

## Real Estate

We work with life sciences companies in the siting, permitting, developing, and financing of new research and manufacturing facilities, as well as developing, leasing and acquiring R&D and laboratory facilities.

## Clients

- Acer Therapeutics
- Alexza Pharmaceuticals
- Align Technology
- Amarantus BioScience Holdings
- Amgen
- Amydis
- Amzak Health Investors
- Aradigm Corporation
- Aridis Pharmaceuticals
- Astex Pharmaceuticals
- Atara Biotherapeutics
- Baxco Pharmaceutical
- Bio-Thera Solutions
- Cardea (formerly Nanomedical Diagnostics)
- Cardiff Oncology
- Cochlear
- CONTINUUS Pharmaceuticals

- CHDI Foundation
- Cresilon
- Decoy Biosystems
- Denali Therapeutics
- DJO Global
- Edwards Lifesciences
- Exeltis USA
- Fera Pharmaceuticals
- Ferro Therapeutics
- FibroGen
- Genentech
- Gilead Sciences
- Global Blood Therapeutics
- Greenwich LifeSciences
- Helix BioPharma
- Hepion Pharmaceuticals
- Hoth Therapeutics
- I-Mab Biopharma
- ImpediMed Limited
- Innovus Pharmaceuticals
- Intuitive Surgical
- JAFCO Life Science Investment
- Kiromic Biopharma
- Kite Pharma
- MatriSys Bioscience
- NeuroBo Pharmaceuticals
- OKYO Pharma
- Oncocyte
- Perrigo
- Plexxikon
- Portola Pharmaceuticals
- Rasna Therapeutics
- Seattle Genetics
- Shanghai Fosun Pharmaceutical Development Co
- Signet Healthcare Partners

- Sunesis Pharmaceuticals
- Sunshine Lake Pharma Co
- Thoratec Corporation
- Tiziana Life Sciences
- Todos Medical
- Unicycive Therapeutics