

## → Life Sciences and FDA

Sheppard Mullin assists clients in the life sciences industry with strategic issues that range from acquisitions to antitrust, entity formation to enforceability evaluations, licensing to litigation, patents to product liability, and trademarks to transfer pricing. 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 from prestigious universities in the areas of biochemistry, cell biology, chemistry, molecular biology, pharmacology, and biomedical engineering enabling us to fully understand our clients' business and objectives.

Our full-service offices serve the life sciences sector in Palo Alto, San Diego/Del Mar, Los Angeles, San Francisco, Orange County, Chicago, Dallas, New York, Washington DC and internationally through our offices in London, Brussels, Shanghai, and Seoul. Attorneys in these offices work with life sciences companies in every phase of their growth cycle.

Sheppard Mullin's Life Sciences team represents biotechnology, medical device, and pharmaceutical companies in a broad cross section of matters, involving one or more of these areas:

### **Antitrust, Competition and Regulatory**

Over the years, our Antitrust, Competition, and Regulatory attorneys have advised a number of the leading originator, biologic, healthcare, and medical devices companies. This experience relates to cartel, abuse of dominance and merger control law, particularly to patent settlements, licensing, originator/generic competition, lifecycle management, R&D, co-marketing/co-promotion agreements, pricing/reimbursement issues, supplemental protection certificates, parallel imports, supply and distribution, quota schemes, and refusal to supply/license.

We also assist clients with advice on all aspects of EU and national pharmaceutical regulation including product safety, clinical trials, dealings with HCPs, manufacturing agreements, product classification, market access, CE marking, data and regulatory exclusivity, and supply and distribution.

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.

Some of our attorneys have previously worked at the European Commission pharmaceutical and cosmetic unit and are, thus, well-connected with the agencies.

## Corporate

### 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.

### 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.

### Securities Law and Corporate Finance

Sheppard Mullin has an active securities and corporate finance practice involving the issuance of securities in registered public offerings and private placements, including venture capital investments and other exempt transactions. We have served as counsel to a variety of issuers/securities underwriting firms and investment banking firms in connection with initial and other public and private offerings of securities. Our attorneys have participated in all aspects of the private placement of securities, representing issuers, private placement agents, equity funds, institutional investors and venture capital firms in every type of private financing transaction, including seed financing angel investments, venture capital financing, later stage equity or mezzanine financing, PIPES and private debt financing. 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.

### Employee Benefits and Executive Compensation

Both public and privately held companies are faced with creating compensation programs for employees and executives in order to attract and retain crucial talent. Many employers have learned that to effectively grow their companies, they must find ways to compensate employees that contribute to the overall success of the company. Sheppard Mullin assists corporate clients to establish tailored incentive and compensation plans to win and keep the employees its competition wants most. We advise on establishing compensation designed to advance company survival and growth interests while at the same time rewarding employees for productive contributions, including dealing with income tax issues. We draft stock option and compensation plans, assist employers in establishing procedures for administering stock compensation plans and advise employers regarding stock compensation plan compliance. We also assist employers in developing tailored bonus and

commission plans that are based on rewards for contribution and increased revenue of an organization.

Our attorneys advise on all aspects of qualified and nonqualified retirement plan and employee benefits matters under the Employee Retirement Income Security Act of 1974 ("ERISA") and the Internal Revenue Code of 1986 (the "Code"), including such matters as defined contribution and benefit plans, profit sharing and 401(k) plans, supplemental executive retirement plans ("SERPs"), Employee Stock Ownership Plans ("ESOPs") and deferred compensation plans, among others.

## FDA Regulatory

We have a full-service FDA team as part of our Life Sciences group. Our attorneys represent companies across an array of industries—pharmaceutical, biologic, medical devices and digital health, food and beverage, 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 comprehensive experience includes advising and assisting our clients on all phases of product development and approval and ensuring compliance with the Federal Food, Drug, and Cosmetic Act; the Public Health Service Act; the Controlled Substances Act; the Food Safety Modernization Act (FSMA); the National Organic Program; and related federal and state laws and regulations.

Our work is vast in scope. It 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—in consultation with our patent colleagues—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 during the Agency's product review, and assist in the preparation for pre-approval inspections. We also partner with clients to handle and resolve post-marketing issues, such as establishment registration and product listing, product safety issues, including adverse event reporting, 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.

## Licensing, 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 attorneys have been representing clients for many years in structuring and negotiating key life sciences arrangements.

We assist in the creation, structuring and negotiation of intellectual property transactions that are so crucial to the success of most life sciences companies. 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 - we have the experience, relationships, and resources available to bring value to our clients throughout the transaction. Our patent 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. They provide "out-of-the-box" thinking related to complex and novel situations. Our attorneys know the latest legal developments and the dynamics surrounding complex life sciences agreements, and we understand the science and technology behind our clients' products and services.

We have substantial experience in drafting and negotiating global clinical trial agreements, Contract Research Organization (CRO) and laboratory agreements, manufacturing 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 with manufacturers and CROs without resorting to legal action.

We have depth and experience in negotiating and structuring license agreements. We regularly represent licensors and licensees in international and domestic transactions involving software, patent, trademark, copyright and trade secret licenses. This experience cuts across a wide range of technologies, and includes highly complex licensing structures. Sheppard Mullin is equipped to address all types of transactions involving our clients' intellectual property, including:

- License Agreements
- Collaborations
- Co-Promotions
- 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

## Labor and Employment

Because life sciences companies operate daily under strict government regulation, the risk of a wrongful termination in violation of public policy suit is greater than with most companies. As easy as it is for an employee to raise one of these claims, it is equally as easy for management to miss the fact that the claim is coming. Because discussions regarding operating procedures, protocols and test results are so common in the life sciences workplace, managers may not realize that the discussion can create a higher risk of employment litigation.

## 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 patent cases, bringing in specific trial skill sets as needed to complement our technical and patent-specific litigation expertise.

We recognize that the majority of IP litigation involves trial and appellate work in the patent area, but it also includes trademark, trade secret, antitrust and unfair competition matters, as well as multi-country patent litigation. Sheppard Mullin is well-equipped to represent clients in each of these types of matters. If early 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.

The firm's 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. 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, 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.

Sheppard Mullin attorneys have also litigated medical device patent cases involving a wide range of technologies. The devices at issue in these cases have included remote glucose monitoring devices, surgical robotics, artificial hips, spinal implants, and cardiovascular stents.

## Patent 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. The key components of our practice are cost-effective work product, responsive service, attention to detail, integrative strategic planning. This gives us the ability to protect our clients' patent technology and to evaluate their competitive positions in the highly competitive life science industry.

We have significant expertise in assisting 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 also have experience searching and analyzing the prior art to evaluate an invention's patentability and to craft patent claims. 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, a sampling of which includes Australia, Canada, China, the European Community, Japan, Korea, Mexico and Taiwan.

In addition to patent prosecution, we offer counseling services to our clients on the complete range of issues that can arise in connection with patent matters. For example, after assisting our clients by patenting their inventions we offer strategic counseling to enable them to exploit their patents through licensing and, where necessary, through enforcement. Because our patent attorneys and agents have substantial experience licensing and enforcing patents, they are better able to write and obtain patents that have value and that will withstand the scrutiny of litigation and licensing negotiations.

We also render opinions concerning the validity, enforceability and infringement of patents. Any company having notice of a patent which may apply to its activities has a legal duty to act with due care for the rights of the patent owner. This duty normally requires that the company obtain a formal opinion of outside counsel to assess whether the patent applies to its activities and is valid. Our expertise in prosecuting and enforcing patents enables us to efficiently and thoroughly review patents and to advise our clients how best to proceed. We review patents to determine whether they have been properly issued and whether they are valid and enforceable. This usually involves a carefully study of the patent, its claims and its 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. Such opinions frequently involve a thorough prior art search, because it is sometimes possible to find highly relevant prior art not considered by the patent examiner.

We also 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. To formulate such an opinion, we normally conduct a thorough prior art search and an initial screening of the search patents to identify any of them that might include claims arguably applicable to the product. We then perform a detailed study of any close patents, to assess the potential for a problem. In some cases, when it is determined that the risk of infringement is substantial, our attorneys will consult with the client to propose and consider various alternative product designs to reduce or eliminate the infringement risk.

## Real Estate

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

## Tax

Sheppard Mullin assists clients in structuring transactions and planning business affairs in order to reduce income, sales, transfer, property and other taxes. A sampling of the matters we handle includes:

- Taxable and tax free mergers, acquisitions and sales
- Venture capital financing and business formation
- Private equity transactions
- Choice of entity and combinations of entities, including C corporations, S corporations, limited liability companies, general and limited partnerships, REITs and cooperatives

- Joint ventures and strategic alliances
- Foreign investment in the United States
- Expansion of U.S. businesses abroad

Our goal is to help our clients achieve their business objectives with practical and effective tax reduction planning. In conjunction with the firm's litigation attorneys, we have also handled tax related matters in state and federal courts and before the United States Tax Court.

## Clients

- Acer Therapeutics
- Aduro BioTech
- Alexza Pharmaceuticals
- Align Technology
- Amaranthus BioScience Holdings
- Amgen
- Amydis
- Amzak Health Investors
- Aradigm Corporation
- Aridis Pharmaceuticals
- Astex Pharmaceuticals
- Atara Biotherapeutics
- Baxco Pharmaceutical
- Bio-Thera Solutions
- Cardea (formerly Nanomedical Diagnostics)
- Cochlear
- CONTINUUS Pharmaceuticals
- CHDI Foundation
- Cresilon
- Denali Therapeutics
- Edwards Lifesciences
- Exeltis USA
- Fera Pharmaceuticals
- Ferro Therapeutics
- FibroGen
- Genentech
- Gilead Sciences

- Global Blood Therapeutics
- Greenwich LifeSciences
- Helix BioPharma
- Hepion Pharmaceuticals
- I-Mab Biopharma
- Immuron Limited
- ImpediMed Limited
- Innovate Biopharmaceuticals
- Innovus Pharmaceuticals
- Intuitive Surgical
- JAFCO Life Science Investment
- Perrigo
- Plexxikon
- Portola Pharmaceuticals
- Rasna Therapeutics
- Seattle Genetics
- Shanghai Fosun Pharmaceutical Development Co
- Signet Healthcare Partners
- Sorrento Therapeutics
- SpineEx
- Sunesis Pharmaceuticals
- Sunshine Lake Pharma Co
- Thoratec Corporation
- Tiziana Life Sciences
- Trovogene
- Vita Therapeutics