



PIONEERING SOLUTIONS. *Helping to bring innovative, life-saving products to the market effectively and efficiently.*

As biotechnology and pharmaceutical companies develop new therapeutics and vaccines, aligning legal strategies with development and commercialization goals throughout the extensive process of funding, R&D, clinical trials and market entry is imperative to a company's strategy, success and growth. We assist clients in developing and implementing plans to protect and expand their pipeline and maximize the benefit of their products to their target patient population.

Duane Morris' Life Sciences and Medical Technologies Industry Group provides practical and creative legal counsel to clients across the globe developing, producing and marketing biologics and drugs. From startups seeking initial capital investment to multinational, publicly traded companies, we provide strategies for developing, protecting and maximizing value and enforcing key intellectual property (IP) rights. Our attorneys assist clients with managing IP risks identified in due diligence and those posed by third parties.

Duane Morris has assisted companies in raising an aggregate of over \$500 million, including from angel investors, venture capital funds, corporate venture arms and public offerings. To foster innovation and entrepreneurship, we work with early stage companies by extending fee-deferral arrangements while they seek prospective investors and strategic partners. We have experience in assisting pharma and biopharma clients with critical partnering, licensing, joint venture and collaboration transactions, as well as creating successful exit strategies. We also counsel these clients on regulatory strategies at every stage of their life cycle, advising on drafting and negotiating agreements relating to pre-clinical and sponsored research, global clinical trials, manufacturing activities and distribution arrangements. We also advise clients on cross-border and customs issues.

Biologic and pharmaceutical clients draw on Duane Morris' trial teams to assert and protect their IP rights in litigation and defend against products liability claims. Our lawyers provide clients with counsel experienced in trade secret, patent infringement, products liability and toxic tort law, including the use of class actions in mass tort litigation, whistleblowing and qui tam actions, and issues arising from acquisitions or licensing disputes.

RANKINGS

- ▶ Ranked by Juristat as a Top 3 Law Firm for Patent Prosecution in Biotechnology and Organic Chemistry
- ▶ Ranked by Legal 500: United States as a **LEADING LAW FIRM** in Life Sciences
- ▶ Ranked by LMG Life Sciences 2022 among leaders in Patent Prosecution



RANGE OF SERVICES

- ▶ IP Licensing/Diligence
- ▶ IP Strategy/Prosecution
- ▶ IP Litigation
- ▶ Regulatory
- ▶ Corporate Formation
- ▶ Financings
- ▶ Exits
- ▶ Stakeholder Disputes
- ▶ Collaborations/Partnering
- ▶ Commercial Contracts
- ▶ Corporate Governance
- ▶ Commercial Litigation
- ▶ Products Liability and Toxic Torts
- ▶ White Collar/Government Regulatory
- ▶ Employment and Labor
- ▶ Benefits
- ▶ Immigration Services and Compliance

FOR MORE INFORMATION, PLEASE CONTACT:

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REPRESENTATIVE MATTERS

IP STRATEGY

- ▶ Represented the seller in the \$485 million sale of royalty stream for ibrutinib to Royalty Pharma.
- ▶ Advised **ALLELE BIOTECH** on global patent strategy and in connection with patent aspects of its licensing agreement to expand Astellas' access to Allele's induced pluripotent stem cell (iPSC) technologies and IP for various cell therapy programs.

IP LITIGATION

- ▶ Represented plaintiff **PERIPHAGEN, INC.** in complex trade secret litigation involving its HSV-1 gene therapy platform. The case settled during discovery with the defendant making an upfront payment of \$25 million, plus potential future payments totaling an additional \$50 million.
- ▶ Represented **AMNEAL PHARMACEUTICALS** against Teva Pharmaceuticals in litigation involving COPAXONE®, the active ingredient of which is glatiramer acetate. Achieved a favorable result after bench trial, which was affirmed on appeal.

REGULATORY

- ▶ Represented a clinical stage biopharmaceutical company in transition to being a commercial stage company in development of a regulatory compliance program in advance of approval and launch of its monoclonal-antibody product.
- ▶ Represented a medical device distributor in navigating the potential FDA recall of products and negotiating resolution of contractual disputes with customers of the distributor.

FINANCING

- ▶ Represented **EVAXION BIOTECH**, a clinical stage biotechnology company specializing in the development of AI-driven immunotherapies to improve the lives of patients with cancer and infectious diseases, in its \$30 million initial public offering.
- ▶ Represented **COMPLEXA INC.**, a clinical stage biopharmaceutical company focused on transforming the treatment of fibrosis and inflammation-associated orphan diseases, in connection with the sale of \$62 million of Series C preferred stock to various investors, including lead investors New Enterprise Associates and Pfizer Venture Investments, LLC.

MERGERS AND ACQUISITIONS

- ▶ Represented the owners of **SOMERSET THERAPEUTICS, LLC** in its \$175 million sale agreement to Par Pharmaceutical, Inc.
- ▶ Represented **CATALENT, INC.** (NYSE: CTLT), a drug delivery technology company, in its \$140 million, all-cash acquisition via tender offer of Juniper Pharmaceuticals, Inc. (Nadaq: JNPR), including its U.K.-based Juniper Pharma Services division.

PRODUCTS LIABILITY

- ▶ Obtained voluntary no-pay dismissals for a pharmaceutical distributor after filing summary judgment motions establishing that our client's over-the-counter talcum powder was not contaminated with asbestos and that the plaintiffs' personal injury claims were preempted by the Federal Food, Drug and Cosmetics Act.
- ▶ National lead counsel for a pharmaceutical manufacturer in the federal, multidistrict National Prescription Opiate Litigation.

COMMERCIAL LITIGATION

- ▶ Represented the stockholders' representatives of a pharmaceutical company in connection with the receipt and

distribution to former shareholders of a \$150 million "milestone" payment from another pharmaceutical company.

- ▶ Represented **DICERNA PHARMACEUTICALS, INC.** defending against claims of trade secret misappropriation brought by Alnylam Pharmaceuticals, Inc., and in bringing counterclaims alleging the lawsuit was brought for the ulterior purpose of interfering with their business, for abuse of process, tortious interference and unfair trade practices.

COLLABORATIONS/PARTNERING

- ▶ Represented **UNILIFE CORP.** (Nasdaq: UNIS; ASX: UNS) in connection with its announced effort to seek strategic alternatives, culminating in a strategic collaboration with Amgen Inc. (Nasdaq: AMGN) for Unilife's wearable injectable drug delivery systems to use with Amgen's biologics and other medicines. The deal provides Unilife with investments of up to \$90 million from Amgen and restructures Unilife's existing debt with OrbiMed.
- ▶ Represented **OLGY BIOSERVICES INC.** in a license amendment with Takeda, which expanded Takeda's commercialization and technology access rights related to Ology's Vero cell technology platform - a cell culture-based platform for vaccine production.

LICENSING

- ▶ Counsel to **ALMIRALL S.A.** in connection with license agreements with Paratek Pharmaceuticals, Inc., pursuant to which Almirall will have exclusive rights to develop, manufacture and commercialize sarecycline products in the U.S. and the greater China region, and Paratek will have the exclusive rights to develop, manufacture and commercialize sarecycline products in all other countries.
- ▶ Represented **THERACOUR PHARMA, INC.**, a research and development pharmaceutical company, in a license agreement with NanoViricides, Inc. (NYSE American: NNVC), a global leader in nanomedicines against viruses. Under the license agreement, TheraCour licensed technology to NanoViricides for VZV, the virus that causes chickenpox in children and shingles in adults.



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