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Life Sciences

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A Focus on the Future

Transformation is the lifeblood of the life sciences industry. Through science and invention. Through research and discovery. Through creation, growth and disruption. Transformative technologies are always pushing the industry beyond its bounds. Whether you are an entrepreneurial startup with a vision of success, an established business with a proven therapeutics solution, or an emerging digital informatics upstart, our focus is on finding the all-embracing business strategies that fit your future.

Pillsbury's Life Sciences practice operates at the intersections of science, technology, business and law, providing clients with custom solutions to unique and complex problems, while helping them achieve their goals. We work with startups, public companies, nonprofit organizations, academic institutions, entrepreneurs and scientists to overcome hurdles and leverage opportunities for the commercialization of life sciences innovations. Our group includes lawyers, scientists and consultants in the leading life sciences corridors of the United States, as well as such major foreign markets as the United Kingdom, Greater China and Japan. Our services cover a wide array of legal issues, including:

- corporate formation and governance
- employment and compensation
- executive compensation and benefits
- international arbitration
- IP litigation
- joint ventures and strategic partnerships
- mergers, acquisitions and exit strategies
- patent portfolio management and prosecution
- public and private securities offerings
- tech transfer and licensing
- venture financing

Corporate Services SCALING YOUR ENTERPRISE

Our experience representing pharmaceutical, biotechnology and medical technology companies is extensive, going back to the landmark initial public offering by Genentech that heralded the acceleration of innovation in the biotech industry. We have advised some of the most scientifically disruptive and successful life sciences companies ever since.

Our corporate team is adept at guiding businesses through major corporate events and transactions, as well as in their day-to-day operations. Our services include the formation and dissolution of joint ventures and other strategic alliances; handling acquisitions and divestitures; and structuring and negotiating joint operating, licensing, distribution, co-promotion, manufacturing and supply agreements.

Landmark Public Offering

Genentech's seminal IPO on Oct. 14, 1980, was "one of the most spectacular market debuts in recent history," according to *The Wall Street Journal*. A year later, Hybritech became the biotech industry's second initial public offering. As leaders and innovators, we participated in both events, and in the IPOs for such influential biotech companies as Cetus, Chiron and Immunex, which pioneered successful business models around scientific research and development.

The Pillsbury Difference

We've walked in your shoes. As former entrepreneurs, scientists, CEOs and inventors, our team members have experienced the dynamic realities of running a life sciences business.

We understand the science. Our global team members have studied the science and technology for pharmacogenomics, bioinformatics, stem cell technologies, transgenics, gene therapies, diagnostics, receptor-ligand interactions, immunomodulators, genetically modified foods and other emerging industry segments.

Technically proficient and experienced. Many team members hold Ph.D.s and other advanced degrees in such fields as cellular biology, biochemistry, molecular biology, microbiology, immunology, chemistry, chemical engineering and physics. Others have served as judicial law clerks for the U.S. Court of Appeals for the Federal Circuit and as U.S. Patent and Trademark Office examiners.

A seamless experience for you. Our team of more than 40 lawyers, scientists and consultants is integrated across disciplines and around the world. They offer an exceptional diversity of experience, business solutions and services.

Well-regarded for our work. Members of the Life Sciences team are distinguished in *Chambers USA, Best Lawyers* and *The Legal 500 U.S.* for services essential to our clients, including M&A, capital markets, venture and emerging companies, intellectual property and litigation.

We Grow with You

As our clients grow, so does our team. We provide the right lawyers to meet the specific needs at every stage of a business's development. With decades of experience, we have assisted entrepreneurs, startups and investors across the life sciences industry.

We have advised more than 1,000 public equity and debt securities offerings with an aggregate value exceeding \$350 billion and more than \$10 billion in venture financings since 2000 for technology and life sciences companies.

Receptos	MediciNova	Genomic Health
\$72,800,000 Initial Public Offering	\$116,000,000 Initial Public Offering (Japan)	\$60,000,000 Initial Public Offering
Incyte Corporation	Invitae	Veracyte
\$650,000,000 Common Stock Offering	\$50,000,000	\$30,000,000

Strategic Transactions

Recognized among the world's top 20 leading M&A advisors by *Bloomberg*, *Factset*, *Mergermarket* and *Thomson Reuters*, Pillsbury offers significant experience to serve our life sciences clients as they execute growth, acquisition and exit strategies in a fast-paced and changing industry.

Salarius Pharmaceuticals,

a company focused on treating rare forms of cancer, in connection with the reverse merger with Nasdaq publicly traded Flex Pharma.

Signal Genetics in its merger with miRagen Therapeutics to create a combined targeted therapeutics and molecular diagnostic company.

Vital Therapies

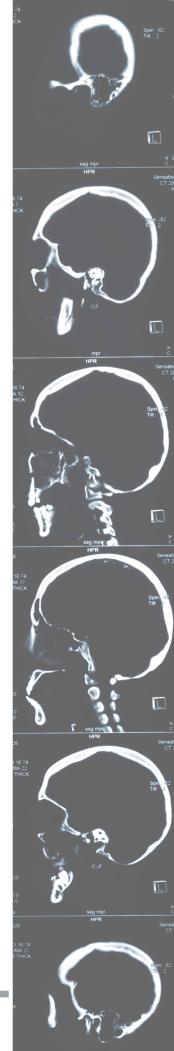
in its merger with Immunic AG to create a leading inflammatory and autoimmune disease company.

Molecular Templates in its merger with Threshold Pharmaceuticals, combining around the development of cancer therapies.

Opexa Therapeutics

in its merger with Acer Therapeutics to focus on developing personalized immunotherapies.

Sentynl Therapeutics, a specialty pharma company, in its acquisition by India-based Cadila Healthcare.



IP Strategies PROTECTING YOUR MOST VITAL ASSETS

Breakthrough products are as essential to life sciences enterprises as the intellectual property that protects them. We help life sciences, biotech and pharmaceutical clients protect and commercialize their intellectual property assets.

Our lawyers understand complex science and quickly translate it for patent law. Serving as strategic IP counsel, our lawyers draw on technical and scientific backgrounds to secure U.S. and international patents for biotechnology companies, to conduct IP due diligence reviews for corporate life sciences transactions, and to close intellectual property deals.

Our strategies for life sciences companies are holistic developing portfolios, capitalizing on the assets, and protecting products and rights.

We Wrote the Books

Editor-in-chief of the quarterly updated and annually reprinted *"The PTAB Handbook*," Bloomberg BNA's all-inclusive guide

Authored chapter in the latest edition of *Perinatal Stem Cells* published by Elsevier entitled, "Patent Protection of Stem Cell Innovations"

Co-authored a chapter in "Pre-ANDA Litigation: Strategies and Tactics for Developing a Drug Product and Patent Portfolio," published by the American Bar Association's Section of IP Law

Marquee Accomplishments

Our IP lawyers work best when the stakes are high, maximizing the IP for life sciences companies.

Capitalizing IP

We advised the Cystic Fibrosis Foundation in a recordsetting \$3.3 billion sale of drug rights to Royalty Pharma following an intensive IP due diligence effort.

Securing Inventorship Rights

In a win for a major U.S. university, we succeeded in adding two researchers as co-inventors on National Institute of Health's patents for Velcade[®], a cancer drug with annual worldwide sales exceeding \$3 billion.

Expedient Defense

Defended Menicon Co. Ltd., a global contact lens manufacturer, favorably resolving infringement claims following a pre-trial hearing.

Patent and Hatch-Waxman Litigation

Our teams have tried patent cases in federal courts throughout the United States and before the U.S. International Trade Commission, involving a variety of pharmaceutical, medical device and life sciences products.

We litigate pharmaceutical drug products on behalf of generic pharmaceutical companies across the globe. Our team of lawyers has collectively handled-including as lead trial counsel-more than 75 Hatch-Waxman litigation matters across the country. Many of these litigation matters were handled on behalf of the world's largest generic pharmaceutical companies.

We have exceptional knowledge of Patent Trial and Appeal Board (PTAB) proceedings and have been able to convince the appeal board to reconsider and reverse its own denials. One such success led to a major pharmaceutical licensing win for IntelGenx, enabling the oral drug delivery company to commercialize a dosing patent.

Record of Experience

- Litigated matters in numerous jurisdictions across the country
- Handled cases through trial, post-trial and settlement negotiations
- Filed first-ever inter partes review challenge of ۰ a pharmaceutical patent
- Successful challenges against brand name drugs Seroquel, Lo Loestrin Fe, Nuvigil and Concerta

Representative Pharmaceutical Products Litigated

Esomeprazole

Fenofibrate

Fesoterodine

Fingolimod

Neurontin®

I amictal

Prevacid

Lamotrogine

Lansoprazole

Levonorgestrel;

Ethinyl Estradiol

LoSeasonique[®]

Linagliptin

Tradjenta®

Linagliptin;

Metformin

Jentadueto[®]

Vyvanse

Apriso

Mesna

Mesalamine

Uromitexan®

Lisdexamfetamine

Gabapentin HCI

Fenoglide

Toviaz®

Gilenya®

Nexium®

Oral Solid Dosages

Alogliptin Nesina®

Alogliptin; Metformin Kazano Alogliptin;

Pioglitazone Oseni® Armodafinil

Nuvigil® Aspirin Dipyridamole Aggrenox®

Azelastine; Fluticasone Dvmista[®]

Balsalazide Giazo®

Bortezomib Velcade

Calcium Acetate Phoslo

Cisplatin Platinol

Carvedilol Coreq CR® Dalfampridine

Ampyra[®] **Darbepoetin Alfa**

Aranesp Desloratadine

Clarinex®

Dimethyl Fumarate Tecfidera®

Drospirenone; **Ethinyl Estradiol** Yasmin®; Yaz®

Aripiprazole Abilify Docetaxel

Taxotere® Erythropoietin Epogen®

Ophthalmics

Moxifloxacin Vigamox®

Travoprost

Travatan 7[®]

Pemetrexed

Alimta

Topical Solutions or Creams

Diclofenac Sodium Pennsaid®

Mupirocin Bactroban®

Synthetic Testosterone AndroGel®

Nelfinavir Mesylate Viracept[®]

Norethindrone Acetate: **Ethinyl Estradiol** Lo Loestrin Fe

Olanzapine Zyprexa®

Pioglitazone Actos[®]

Quetiapine Seroquel®

Roflumilast Daliresp®

Saxagliptin Onglyza

Saxagliptin; Metformin Kombiglyze[®]

Sildenafil Viagra®

Tranexamic Acid l vsteda

Valganciclovir Valcyte

Vortioxetine Trintellix®

Concerta[®]

Methylphenidate HCl

Modafinil Provigil®

> Naproxen Sodium Naprelan®

> > Gemcitahine

Gemzar®

Paclitaxel

Ahraxane

Tafluprost

Zioptan®

Aloxi

Palonosetron

Patent Prosecution

Our lawyers use scientific and technical backgrounds to secure broad patent protection for life sciences companies. Patent strategies cover diverse fields, including pharmacogenomics, bioinformatics, stem cell technologies, transgenics, gene therapies, diagnostics, receptor-ligand interactions, immunomodulators, genetically modified foods and other emerging industry segments.

On average, we file more than 3,900 patent applications and obtain nearly 1,600 patents for clients annually, manage thousands of domestic and international patents and help optimize patent value through licensing arrangements.

A Client's World-Changing Technology

Brain Chemistry Labs may be closing in on a breakthrough treatment for Alzheimer's disease. *Fortune* reported that the company's research into ethnobotany poses a new theory and alternative to the approach of Big Pharma. The company's relationship with Pillsbury goes back 20 years. That's when our lawyers achieved a breakthrough in securing an elusive patent. As strategic IP counsel, we have developed and now manage Brain Chemistry Labs' large patent portfolio, exciting work for an unconventional company.

Global Services WORKING ACROSS THE INDUSTRY

Life sciences is a global industry, and doing business often requires in-depth knowledge of many sets of rules and regulations. Pillsbury draws on a full platform of services to meet the disparate needs in the industry, from emerging biotech to global pharmaceutical companies to their partners in health care. We handle international arbitrations; help clients obtain and enforce U.S. and international IP protections (filing and prosecuting thousands of patent applications annually); and work tirelessly to protect trade secrets and other intellectual property rights. Further, our skilled litigators stand ready to protect life sciences clients' rights in disputes all around the world.

Global Sourcing & Technology Transactions

Our technology transaction lawyers regularly advise pharma clients on major IT outsourcing transactions and have ample experience negotiating Quality Agreements with pharma supply chain actors, as well as services agreements for contract manufacturing and clinical trials.

Foreign Corrupt Practices Act & Global Anti-Corruption

Pillsbury advises on U.S. anti-corruption law and other anti-bribery mandates across the globe, aiding pharmaceutical and other medical-related manufacturers facing U.S. Foreign Corrupt Practices Act and export control actions. In addition, we defended the United Kingdom's first serious fraud prosecution relating to cartel activity in the generics drugs industry.

False Claims Act Investigations

Pillsbury can help to ensure that companies at risk of investigation for fraud adhere to False Claims Act provisions in the first instance. We defend against False Claims Act claims and allegations, and handle communications and negotiations with the U.S. Department of Justice.

Employment Law

Members of our employment practice advise on protection of trade secrets and proper employee wage and hour classifications. Team members are experienced in defending clients in litigation involving allegations of discrimination, failure to accommodate and wrongful termination.

Executive Compensation & Benefits

Our lawyers have more than 30 years of experience advising global pharma, life sciences and biotech industry companies on executive and employee compensation and benefits issues.

International Arbitration

We offer decades of experience adjudicating disputes administered by international arbitral institutions worldwide. We represented a pharmaceutical company in International Chamber of Commerce arbitration to determine ownership, trade secrets and enforcement rights regarding biotechnology materials and related patents.

Firm Awards & Accolades

We are proud to be recognized for legal excellence and service to clients.

Nationally ranked for Startups & Emerging Companies Chambers USA 2019

M&A Law Firm of the Year, small to mid-market *M&A Atlas Americas* 2018

Top-tier for Securities / Capital Markets and for Venture Capital *U.S. News & World Report – Best Lawyers* "Best Law Firms" 2019

Top-tier for Intellectual Property U.S. News & World Report – Best Lawyers "Best Law Firms" 2019

Nationally recognized for patent prosecution The Legal 500 U.S. 2018

Top 20 among Client Service A-Team firms; Most Recommended by General Counsel *BTI Consulting,* 2018 and 2019



About Pillsbury

Pillsbury Winthrop Shaw Pittman LLP is an international law firm with a particular focus on the technology & media, energy, financial services, real estate & construction, and travel & hospitality sectors. Recognized by legal research firm BTI Consulting as one of the top 20 firms for client service, Pillsbury and its lawyers are highly regarded for their forward-thinking approach, their enthusiasm for collaborating across disciplines and their unsurpassed commercial awareness.

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Learn More

To learn more about our Life Sciences practice, please visit us at: **pillsburylaw.com/life-sciences**

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