HUSCH BLACKWELL

LIFE SCIENCES

Our Life Sciences team advises life sciences companies of all sizes, from startups to large investors, and all types: our client roster includes pharmaceutical companies, medical device manufacturers, biotechnology programs, and digital health providers. While many attorneys in the life sciences space focus solely on intellectual property protection, we provide guidance throughout companies' life cycle, partnering with our clients through business formation, financing, research, clinical trials, patent prosecution, data privacy, regulatory compliance, litigation, and exit planning. Our services are as diverse as our clients.

Life sciences regulatory

Our regulatory life sciences attorneys—many of them with backgrounds as research scientists—are deeply familiar with the laws governing drug development, technology licensing, and clinical trials. We routinely assist clients in taking new drugs and technologies from early research to final regulatory approval, as well as in navigating the complex data privacy questions inherent in digital health and telehealth.

The team is equally well-versed in the Food and Drug Administration (FDA) requirements for medical devices, pharmaceuticals, biotechnology, and radiation-emitting electronic products—and when things go wrong, we're on hand to advise on enforcement matters. Our Life Sciences practice also includes a Psychedelics & Emerging Therapies team knowledgeable about this novel and rapidly growing area of drug development.

"The Husch Blackwell attorneys were fierce and tireless advocates for Virtus. In the face of aggressive actions by our competitors and FDA regulators, they developed and executed a legal plan that protected an important market for us. They have my gratitude and highest recommendation."

— Tina Guilder, CEO, Virtus Pharmaceuticals —

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Life sciences litigation

Our attorneys are highly experienced representing life sciences clients in court. We regularly litigate patent infringement cases, post-grant proceedings, Hatch-Waxman Act disputes, ITC cases, and other IP litigation, defending clients' intellectual assets, and we have handled injunction hearings, Markman proceedings, trials, and appeals. We have also successfully represented numerous clients in Abbreviated New Drug Application (ANDA) litigation, as they seek to introduce generic competition to the marketplace in the face of brand-name patents.

Life sciences corporate transactions

We're leaders in the corporate transaction space, representing clients across industries in multimillion and billion-dollar mergers, acquisitions, divestitures, joint ventures, and strategic alliances—and we handle these deals in the life sciences world as well. Our attorneys have counseled telehealth and digital health providers, software and AI companies, technology and service providers to the healthcare industry, medical devices manufacturers, and biopharma therapy providers in corporate transactions. We also represent life sciences clients in a wide variety of capital markets transactions, including public and private debt and equity offerings, as well as associated securities and regulation compliance and corporate governance concerns.

Representative Experience

Regulatory

Researched and drafted briefing on federal preemption issues on behalf of leading global medical device

manufacturer surrounding pharmaceutical and healthcare products.

Advised higher education client on federal regulations and California law governing who is able to prescribe, administer and dispense controlled substances under California law, information needed for DEA licensing requirements, and clinic licensing requirements for human studies involving psychedelic substances.

Advised business on current state and federal drug paraphernalia laws and liability issues related to psychedelic substances.

Advised venture capital firm as to liability risks associated with proposals that could implicate international treaties on psychedelics.

Advised author as to liability issues related to contract with publisher and drafted disclaimer language for author's book related to psychedelic-assisted therapy.

Provided advisory services related to developing a ketamine clinical network.

Prepared informed consent documents to comply with healthcare regulations for therapy practice utilizing new technology.

Represented healthcare practitioner to negotiate and resolve claims associated with a therapeutic instrument.

Provided analysis of company drug discovery regulatory files in order to provide a due diligence evaluation that would enable potential investors to understand potential

risks involved that could impact the business.

Assist clients with digital health software matters, including requirements for design controls, mobile medical apps, exemptions for medical software, and compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Created and implemented an administrative review process for human research studies for a large health system, including development of related policies and procedures.

Advised clinical trial and institutional review boards (IRBs) on compliance matters.

Organized and supervised clinical trials for early-stage biotechnology company.

Led top-to-bottom review and enhancement of medical device manufacturer's compliance program, including clinical trials and investigation policies, procedures, and implementation.

Drafted and negotiated clinical trial agreements with principal investigators, institutions, sponsors, SMOs, and CROs.

Drafted and negotiated royalty agreements between manufacturers and physicians.

Assisted preeminent research facility with the development of COVID testing innovation and research strategy, including analysis of FDA, EUA, laboratory developed tests, and PREP Act implications and community outreach

contracts.

Advised national laboratory on licensing, CLIA, and FDA regulatory issues related to COVID-19 screening and surveillance procedures using its FDA-authorized diagnostic test, and analyzed impact on PREP Act immunity.

Assisted in the conversion of an animal laboratory to a human laboratory in the areas of CLIA, licensure, privacy, and billing matters.

Helped evaluate compliance with federal research regulations (informed consent/IRB issues), National Institutes of Health Grants Policy Statement (NIHGPS), and related federal regulations and investigations in area of pediatric and adult research.

Assisted in the sale of a nutrigenomic laboratory to provide healthcare regulatory due diligence guidance to minimize risk.

Litigation

Successfully represented the complainant, Ventria Bioscience Inc., in *Certain Plant-Derived Recombinant Human Serum Albumins & Products Containing Same*, Inv. No. 337-TA-1238, a case involving patent infringement and false designation of origin against a Wuhan, China-based competitor (a company founded by a former employee of Ventria) and its U.S. distributors. The case went to trial in November 2021. In September 2022, the ITC found all respondents in violation of Section 337 and issued remedial orders that exclude the infringing and mislabeled products from the U.S. market. This high-profile case dovetails with

broader policy issues between the U.S. and China relating to trade and intellectual property; as such, it attracted attention from the media and from many bipartisan elected officials and trade groups.

Successfully defended Sigmapharm Laboratories, LLC in connection with its application for approval of a generic version of the antidepressant vortioxetine.

Advised leading biosimilar client regarding litigation strategies for multiple biopharmaceuticals subject to the Biologics Price Competition and Innovation (BPCIA) Act.

Aided client FlatWing Pharmaceuticals in demonstrating that 39 claims in 4 patents filed by competitor were unpatentable.

Represented TWi Pharmaceuticals, Inc. in a patent infringement case alleging its generic version of Par Pharmaceutical's Megace ES infringed Alkermes' (formerly Élan) patent for nanocrystal megestrol acetate. After a seven day bench trial, the court entered judgment for TWi in February 2014 finding Alkermes' patent invalid as obvious. Par, Alkermes v. TWi, 2014 WL 694976 (D. Md.)

Represented Amerigen Pharmaceuticals, Ltd. in a patent infringement case alleging its generic version of Shire LLC's Adderalll XR infringed several patents. The case was favorably settled after three days of trial. Shire v. Amerigen (D.N.J.)

Represented TWi Pharmaceuticals Inc. in a patent infringement case alleging its generic version of Cephalon's

Amrix infringed several patents. After conducting a seven day bench trial, the court issued an opinion in May 2011 finding that TWi's product did not infringe any claims of the '793 and '372 patents and entered judgment in its favor. Following the decision, TWi filed a motion to deem the case exceptional and for fees. The court granted TWi's motion and awarded TWi attorneys' fees. In re Cyclobenzaprine Hydrochloride Extended Release Patent Litigation (D.Del. 2012)

Represented Virtus Pharmaceuticals, Inc. in litigation at the International Trade Commission (ITC) alleging Virtus' potassium chloride products unfairly competed against similar products marketed by Par Pharmaceuticals. The case settled favorably after Virtus filed suit against FDA challenging the agency's enforcement policies applicable to potassium chloride products. In Matter of: Certain Potassium Chloride Products (ITC); Virtus v. FDA (M.D. Fla)

Represented Teh Seng Pharmaceutical Mfg. Co. Ltd. and TWi Pharmaceuticals Inc. in a patent infringement case alleging their generic version of Endo's Lidoderm transdermal patch infringed several patents. The case was favorably settled on the eve of trial. Endo, Teikoku v. TWi, Teh Seng (D. Del. 2014)

Represented TWi Pharmaceuticals, Inc. in a patent infringement case alleging its generic version of Purdue's Intermezzo infringed several patents. After trial appeal, the patents were found invalid as obvious. Purdue

Pharmaceuticals v. TWi (D. N.J. 2015)

Represented TWi Pharmaceuticals Inc. (and its predecessor Anchen Pharmaceuticals Inc.) in a patent infringement case alleging its generic version of Shire's Intuniv infringed several patents. The case was favorably settled after the filing of a motion for summary judgment. Shire v. Anchen, TWi (D.Del. 2012)

Represented MedPharmex in a patent infringement case regarding its generic version of Merck's animal drug Mometamax. After initial proceedings, the Court entered a judgment of noninfringement in favor of our client.

Represented Anchen Pharmaceuticals Inc. (now Par Pharmaceutical) in a patent infringement case involving its generic version of Jazz's Luvox CR. The case was favorably settled after filing a motion for summary judgment. Elan, Jazz v. Anchen (C.D. Cal. and D. Del. 2010)

Represented Anchen Pharmaceuticals (now Par Pharmaceutical)in a patent infringement case alleging its generic version of Biovail's Wellbutrin XL infringed several patents. The court granted Anchen's motion for summary judgment finding that Anchen's product did not infringe any Biovail patent. Biovail also made two attempts to seek an injunction against the Food and Drug Administration (FDA) to prevent approval of Anchen's Abbreviated New Drug Application (ANDA) product, both of which were denied. Anchen launched its generic product in December 2006. Biovail Labs v. Anchen (C.D. Cal. 2006)

Successfully defended pharmaceutical manufacturer in U.S.

International Trade Commission (ITC) against competitor's claim that generic drug was marketed unfairly.

Aided Sigmapharm Laboratories in arguing for claim construction. Court adopted proposed construction verbatim.

Secured victory for TruPharma, LLC in federal court litigation brought by a competitor alleging false advertising and unjust enrichment, among other counts, in connection with the manufacture and sale of a medical cream. Complaint dismissed with prejudice.

Forest Labs, et al. v. Teva Pharmaceuticals USA, Inc., et al., 14-cv-00121 (D. Del.). Served as lead trial counsel representing world's largest generic drug company in patent infringement dispute relating to generic company's attempt to market generic version of $2.2 billion blockbuster Alzheimer's drug, Nameda XR, before patent expiration. An analyst attending the trial reported that Jeff's cross-examination of the brand company's main expert witness "drew blood on almost every point." After the trial was over, but before decision, the case settled favorably for the generic company under confidential terms.

Purdue v. Teva Pharmaceuticals USA, Inc., 14-cv-02357 (S.D.N.Y.) Part of a team that secured a victory for a large pharmaceutical company in a patent infringement case involving oxycontin. Successfully argued that four of plaintiff's patents lacked novelty or were obvious; fifth patent was ruled invalid for indefiniteness. Client secured favorable settlement.

Hoffmann-La Roche v. Teva Pharmaceuticals USA, Inc., 09-cv-5283 (D. N.J.). Lead trial counsel in a Paragraph IV Hatch-Waxman case representing a pharmaceutical company concerning its ANDA for capecitabine (Xeloda®). Challenged the infringement and validity of listed Orange Book patents; case settled on favorable terms on the eve of trial.

OSI Pharmaceuticals, Inc., Pfizer, Inc. And Genentech, Inc. v. Teva Pharmaceuticals USA, Inc., et al., 09-cv-00185 (D. Del.). On a team representing a pharmaceutical company against charges of infringement of compound, polymorph and method patents relating to erlotinib (Tarceva®) in a Paragraph IV Hatch-Waxman case. Client was offered a favorable settlement on the first day of trial.

Celgene v. Teva Pharmaceuticals USA, Inc., 04-cv-04030 (D. N.J.). Lead trial counsel in a Paragraph IV Hatch-Waxman case over its efforts to introduce a generic version of Focalin® (dexmethylphenidate) into the consumer market. Achieved a successful settlement for the defendant.

Astra v. Kremers Urban Development Co. and Schwarz Pharma., 99-cv-08928 (S.D.N.Y.). Part of a team representing Kremers Urban Development Co. and Schwarz Pharma in support of their ANDA seeking permission to launch a generic version of Prilosec® onto the market. The drug was netting around $10 million per day. Achieved a successful decision for clients in multidistrict litigation, finding no infringement, and permitting clients to introduce a generic version of the drug.

Transactions

Served as counsel to a Fortune 500 medical device company in connection with the company's strategic investment transactions.

Served as counsel to a privately held, North Carolina-based spine medical device company in connection with a merger transaction with a Florida-based, publicly held medical device company.

Served as counsel to a United Kingdom public limited company in connection with the company's acquisition of the ear, nose, and throat business of a publicly held, Tennessee medical device company.

Served as counsel to a publicly held pharmaceutical company in connection with a merger transaction involving a privately held, New Jersey-based pharmaceutical manufacturer.

Served as counsel to a privately held, Minnesota-based orthopedics company in connection with the company's venture and strategic investment transactions.

Served as counsel to a privately held, Midwest based medical device AI imaging and diagnostic company in connection with strategic investment and commercial transactions.

Advised on creation and design of B2B and B2C business model for national behavioral telehealth technology company. Model was tailored to comply with federal and applicable state legal and regulatory requirements,

including telehealth, corporate practice, fee splitting, privacy and security, and corporate formalities.