

Overview

You face more governmental scrutiny and market pressure than ever before. Health care reform, increased competition, stricter governmental enforcement (civil and criminal), and the expiration of patents for major products place enormous pressure on the pharmaceutical sector. Over the last decade, delivery of new products to market has become increasingly costly and challenging.

Dentons has you covered. We can help you navigate all phases of your business, from financing and protection of intellectual property, to clinical trials, product manufacturing and drug coverage, through regulatory issues and product problems, we work with you to find solutions. To help you stay ahead, we track the latest developments in new technology investment, licensing of new compounds, teaming arrangements and industry consolidation.

Over the past several decades, our lawyers have worked hand in hand with pharmaceutical clients on some of the industry's most important drug development transactions, patent cases, financings and licensing transactions. We have walked with clients through regulatory complexities and, when roadblocks appeared in the guise of investigations, litigation and government inquiries, our team helped clients find business-oriented solutions.

Leverage our deep bench strength to deliver cutting-edge solutions to meet your diverse needs, wherever they may arise around the globe. Let us work hand in hand with you through the challenges of reform, competition and regulation.

Representative Experience

- **A&D Pharma:** Advising the largest integrated pharmaceutical wholesale and retail business in Romania in connection with its admission to trading on the Main Market of the London Stock Exchange. The project received the Deal of the Year Award from the Diplomat monthly publication and is the first listing of a Romanian company to the Main Market of London.
- **One of the largest brand pharmaceutical companies:** Serving as US regulatory and compliance counsel and as anti-corruption, FCPA and product protection counsel on a global basis for one of the largest brand pharmaceutical companies on the globe.
- **Japanese based pharmaceutical company:** Advising on a complex multijurisdictional regulatory review in preparation for its new product-licensing launch in the Middle East.
- **Fortune 100 pharmaceutical and device manufacturer:** Providing day-to-day fraud and abuse counseling in connection with its ownership of, and compensation arrangements with, providers, suppliers, practitioners, physicians and patients.
- **Fougera Pharmaceuticals, Inc.:** Defending an AWP case filed in the State of Louisiana against the client and dozens of other pharmaceutical companies in East Baton Rouge, Louisiana. Our team was able to obtain a favorable settlement.
- **GlaxoSmithKline:** Representing in a qui tam whistleblower litigation, alleging violations of the US False Claims Act in connection with the drug Paxil, and seeking billions of dollars in damages. Our team convinced the court, at an early stage in the litigation, to dismiss the whistleblower's case in its entirety with prejudice and without an opportunity to amend. Indeed, our team not only convinced the court, but also convinced the US Department of Justice to support our position in seeking dismissal.
- **Important pharmaceutical company:** Representing before the Commercial Court of Nanterre, in a litigation

proceeding initiated by another pharmaceutical company in relation to the consequences and settlement terms of the termination of a longstanding quasi-worldwide contract for the distribution of the other pharmaceutical company's products; the dispute consists of alleged breaches and requests for forced production of documents; the alleged damages are claimed to be up to €20 million.

- **K-V Pharmaceutical Company:** Acting as national coordinating and lead trial counsel for a series of individual, multi-plaintiff, and class action product liability cases related to product recalls occurring in 2008 and 2009. Defending these cases at the trial and appellate level in the federal and state courts in at least 24 states, leanly staffing the matters with a core team from its Dallas office, and drawing also upon the expertise of lawyers in its own offices in Chicago, New York, New Jersey, Los Angeles, San Francisco, Washington, DC, St. Louis, Kansas City, and Phoenix, our team was able to use its broad experience in the pharmaceutical industry, product liability, class action defense, health care, and consumer protection to strategize across disciplines and jurisdictions and provide the client a coordinated defense and comprehensive service. The cases have been largely resolved to the company's satisfaction via dismissal or following early case assessment and resolution. Most recently, there were two major victories involving class actions. In *Lefavre/Polk v. KV Pharmaceutical Co.*, our team obtained a second dismissal of the case in which the alleged class of plaintiffs claimed economic injury based upon their purchase of a drug that was later recalled by the company. This case had previously been dismissed, the dismissal was reversed by the Eighth Circuit, and upon remand our team again obtained a dismissal. In *Herndon v. KV Pharmaceutical Co.*, our team defeated class certification in a case in which the alleged class of plaintiffs claimed economic injury based upon their purchase of a number of drugs that were later recalled by the company. Class certification was denied after discovery, briefing and argument in March of 2012.
- **KV Pharmaceutical:** Coordinating and lead trial counsel for a series of individual, multi-plaintiff, and class action product liability cases related to product recalls occurring in 2008 and 2009. Defending these cases at the trial and appellate level in the federal and state courts in at least 24 states, leanly staffing the matters with a core team from its Dallas office, and drawing also upon the expertise of lawyers in its own offices in Chicago, New York, New Jersey, Los Angeles, San Francisco, Washington, DC, St. Louis, Kansas City, and Phoenix, our team was able to use its broad experience in the pharmaceutical industry, product liability, class action defense, healthcare, and consumer protection to strategize across disciplines and jurisdictions and provide the client a coordinated defense and comprehensive service. The cases have been largely resolved to the company's satisfaction via dismissal or following early case assessment and resolution. Most recently, there were two major victories involving class actions. In *Lefavre/Polk v. KV Pharmaceutical Co.*, our team obtained a second dismissal of the case in which the alleged class of plaintiffs claimed economic injury based upon their purchase of a drug that was later recalled by the company. This case had previously been dismissed, the dismissal was reversed by the Eighth Circuit, and upon remand our team again obtained a dismissal. In *Herndon v. KV Pharmaceutical Co.*, our team defeated class certification in a case in which the alleged class of plaintiffs claimed economic injury based upon their purchase of a numbers of drugs that were later recalled by the company. Class certification was denied after discovery, briefing and argument in March of 2012.
- **Patheon Inc.:** Acting as counsel on the Canadian aspects of Patheon's October 2012, CA\$255 million deal with Netherlands-based VION N.V. to purchase its specialty pharmaceutical division, Banner Pharmacaps. This included the handling of the environmental and regulatory due diligence associated with the Canadian assets and operations.
- **Scil Technology GmbH:** Advising on the out-licensing of certain intellectual property portfolio for the regenerative treatment of inter alia osteoarthritis to Sanofi, including the structuring of the licensing strategy, negotiating the complex license agreement, and the monitoring of all additional activities following the execution of the agreement.
- **Warner Chilcott:** Assisting a US pharmaceutical group specializing in feminine health and skin care on all French aspects of the acquisition of the worldwide ethical pharmaceuticals division of Procter & Gamble. We also advised Warner Chilcott in Germany and Spain. Worldwide transaction value was estimated at \$3.5 billion. Since then Warner Chilcott decided to reorganize substantially its European activities, and we have been advising on all corporate, commercial, regulatory and labor aspects of its 2011/2012 reorganization in France.