

Overview

Businesses that develop new medical treatment technologies, whether pharmaceutical products or medical devices, operate in an environment where the confluence of technological advancements, evolving government policy and changes to the legal landscape make risks unavoidable.

At Dentons, our lawyers have the deep industry knowledge and keen legal expertise to help you manage these risks. From investigations by regulatory agencies to insurance coverage disputes to defense of mass product liability class action claims, we partner with you to thoughtfully develop and implement the right approach to overcome challenges to your business' success.

Our team stands at the ready to respond with swiftness and agility to effect a coordinated risk management or dispute resolution strategy, throughout the global reach of your business.

Representative Experience

- **Bioton S.A.:** Representing a leading Polish life sciences company in an international patent dispute with a foreign competitor. We were litigating and simultaneously advising on formulating the relevant communication strategy for the market. Legal measures taken by the adversary created a threat to both distribution and sale of the client's core product and were accompanied by a negative public relations campaign against it. By an immediate and top-quality reaction to the injunction granted by the court and consecutive 100% successful appeal, we have protected the company from irreparable damages in a very complex matter as it relates to patent infringement issues, misuse of rights, medical devices law and reimbursement issues.
- **Global Biopharmaceutical Company:** Representing client in Texas state court (along with the plaintiff's doctor) in a product liability action relating to its anti-inflammatory drug. After responding to only minimal discovery, we moved for summary judgment, relying on the learned intermediary doctrine. When the plaintiff non-suited all claims just prior to the hearing on this motion, our client was dismissed from the suit. Because the statute of limitations has expired, the dismissal was with prejudice.
- **Cross-border anti-corruption investigation:** Represented Fresenius Medical Care AG & Co. KGaA, a global health care/medical device company with operations in more than 150 countries, in connection with parallel SEC and the DOJ investigations into multiple alleged violations of the FCPA in Asia, Africa, Europe, and North and South America. Working with our locally based practitioners, our global team helped the client respond to this cross-border investigation and implement new global anti-corruption policies and procedures. The Dentons team ultimately resolved the US criminal inquiry through a non-prosecution agreement with the DOJ and a regulatory order by the SEC.
- **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.

- **KV Pharmaceutical Co.:** 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, 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.
- **Nation's largest privately held pharmacy benefits manager:** Won dismissal in the US Court of Appeals for the Eleventh Circuit of the US\$600 million antitrust claims by independent pharmacies in Alabama who alleged that the pharmacy benefits manager possessed monopsony power based on its administration of Alabama's Public Education Employees' Health Insurance Plan. That court agreed plaintiffs did not present sufficient evidence of harm to competition or that our client had monopsony power. Class certification had been denied two years earlier.

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