

Overview

You live and work in a highly regulated, complex industry. Your people are working hard to develop, manufacture and produce lifesaving products and technologies. Even in companies of the highest integrity, with state-of-the-art business and manufacturing practices and stringent quality control, disputes arise, investigations ensue and lawsuits are filed. When that happens, you need a savvy team who knows your industry, understands the regulatory framework in which you operate, and cares as much as you about the outcome.

Benefit from Dentons' years of experience. Our lawyers and professionals work alongside life sciences clients to resolve a myriad of disputes in arbitration, mediation or trial. Our litigators have the depth of industry knowledge and seasoned expertise in mass tort claims to develop and implement a coordinated defense strategy in jurisdictions across the globe.

When disputes arise with competitors, you can tap our significant patent, distribution, supply, promotion, licensing and unfair competition dispute expertise. We work with you on strategies for handling disputes with governmental authorities, agencies and public entities, regarding:

- Drug coverage and reimbursement
- Average wholesale pricing
- False Claims Act
- Medicare and Medicaid fraud
- Off-label marketing and advertising sanctions
- Pharmacovigilance duties and sanctions
- False health claims
- Good manufacturing practices.

Highly regulated clinical trials require particular knowledge—especially of issues involving patient consent and injuries during clinical trials. Our lawyers have the knowledge and experience across multiple geographies to tackle disputes and litigations arising from clinical trials. And when product claims are made, our Product Liability and Product Recall teams have the capability to handle disputes of any magnitude and number. With Dentons at your side, your ability to focus on your business will be beyond dispute.

Representative Experience

- **Amway GmbH:** Advising the world's leading direct sales company on all trademark applications, trademark disputes, and intellectual property related matters in Turkey.
- **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.

- **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.
- **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.
- **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.