

Generic Pharmaceuticals

Kelley Drye's Generic Pharmaceuticals Team has a deep understanding of the generic pharmaceutical industry, earned over a two-decade partnership working alongside generic companies. We offer clients legal counsel grounded in a strong knowledge of sales, marketing, pricing practices, patents, trademarks, the inner workings of Medicare, Medicaid and private insurers, and the competitive pharmaceutical industry landscape.

About

Kelley Drye serves generic pharmaceutical clients in the following areas:

- Antitrust and Pricing
- Fraud, False Claims, Consumer Protection and Deceptive Trade Practices
- Contracts
- Products Liability and Opioids
- Patents – Hatch Waxman
- Patents – Medical Devices
- Labor and Employment
- Advertising Law Litigation and Counseling
- Export Controls and Sanctions Compliance

Experience

Antitrust and Pricing

- Representing a generic pharmaceutical company in the multidistrict antitrust litigation, *In re Generic Pharmaceuticals Pricing Antitrust Litigation*. This MDL includes actions brought by state attorneys general, private class action plaintiffs, and individual private party plaintiffs.
- Representing generic pharmaceutical companies in a “pay-for-delay” antitrust litigations and investigations.
- Represented a generic pharmaceutical company in an action concerning the enforcement of a Hatch-Waxman settlement agreement.
- Counseling generic pharmaceutical companies on the setting of published prices and contract prices.
- Counseling generic pharmaceutical companies on the creation of pricing and antitrust policies.

Fraud, False Claims, Consumer Protection and Deceptive Trade

Practices

- Representing multinational generic pharmaceutical manufacturers in numerous federal and state actions across the country, concerning alleged violations of federal and state false claims acts, state consumer protection and deceptive trade practices acts, false advertising acts, and common law fraud in connection with the Medicaid and Medicare programs and private insurance health plans. These actions have included qui tam litigation, class action litigation, and actions brought by the United States Department of Justice and state attorneys general.
- Representing multinational generic pharmaceutical manufacturers in state attorney general action concerning covered outpatient drugs.
- Counseling pharmaceutical manufacturer on product disparagement claims.

Contracts

- Representing generic pharmaceutical companies in breach of contract actions involving the manufacturing, supply and marketing of drugs.
- Representing generic pharmaceutical companies in the negotiation of contracts with wholesalers, pharmacies, group purchasing organizations, suppliers and other customers and vendors.
- Represented generic pharmaceutical company in negotiating co-development agreements.
- Represented generic pharmaceutical companies in breach of contract action relating to asset purchase.
- Represented generic pharmaceutical companies in breach of contract action with device supplier.

Products Liability and Opioids

- Obtained a dismissal of all claims against a generic pharmaceutical company in the multidistrict litigation, *In re: Zantac (Ranitidine) Products Liability Litigation*.
- Representing a generic pharmaceutical company in the multidistrict litigation, *In re: National Prescription Opiate Litigation*.
- Counseling multinational generic pharmaceutical manufacturers on insurance coverage, drug acquisitions, and reporting obligations.

Patents – Hatch Waxman

We have represented multinational generic pharmaceutical manufacturers in Hatch-Waxman patent litigation, trials and appeals, concerning the following drugs:

- aripiprazole
- asenapine maleate
- celecoxib
- metformin ER
- methylphenidate
- mirtazapine

- cisplatin
- esomeprazole
- eszopiclone
- gabapentin
- iloperidone
- imatinib
- lanthanum carbonate
- levoleucovorin injection
- loratadine
- memantine HCl
- memantine HCl ER
- levoleucovorin injection
- memantine HCl
- memantine HCl ER
- metaxalone
- mixed amphetamine salts
- modafinil
- pitavastatin calcium
- testosterone undecanoate
- testosterone gel
- omeprazole
- oral contraceptives
- oxaliplatin
- prasugrel
- quetiapine
- ropivacaine injection
- zolpidem tartrate sublingual

Patents – Medical Device

- Represented generic pharmaceutical company in Hatch-Waxman patent litigation concerning intravenous bags used with ropivacaine HCl injection.
- Counseled generic pharmaceutical company concerning a biosimilar drug and injection device.
- Represented a major consumer electronics and medical device maker in patent infringement and antitrust suit involving 24 patents on pulse oximetry technology.
- Represented one of the world's largest manufacturers of contact lenses in an infringement lawsuit concerning a patent on extended-wear lenses.
- Provided strategic advice and management of the worldwide patent and trademark portfolio for a client designing medical devices for use in the treatment of and operation on the body's distal extremities.
- Represented medical device company against claims of infringement of patents covering surgical guides used during knee implant surgery.
- Represented manufacturer of cosmetic lasers in patent infringement litigation.

Labor and Employment

- Counseling multinational generic pharmaceutical manufacturers on employee disputes and internal management of employees.

Related Services

False Claims Act Defense

Patent Litigation and Post-Grant Proceedings

Corporate and Tax

Patent Prosecution

Contacts

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