

Hatch-Waxman Litigation

Overview

Global pharmaceutical companies turn to Dentons' team of professionals in the life sciences sector. Dentons' practice covers the entire life cycle of a drug—from clinical trials to patent trials, including litigation arising from the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act).

Our Hatch-Waxman litigation experience on behalf of generic pharmaceutical companies spans the full range of related issues, including not only litigation through trial and appeal, but also assisting in the development of pre-litigation strategy, including non-infringement opinions, assisting with development of strategy for paragraph iv certifications, notice letters and OCAs (offers of confidential access). Our team members have worked with numerous generic pharmaceutical companies on wide variety of pharmaceutical products in abbreviated new drug application (ANDA) patent litigations, as well as 505(b)(2) applications. We understand that each situation is different, and we work closely to develop customized strategies and corresponding legal budgets to maximize the chance of success in light of all relevant factors, including the strength of defenses, the size of the market, and the client's filing priority.

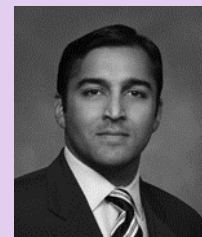
Our core team includes experienced trial attorneys who have mastered the law and rules of courts, and understand the intricacies of the issues that frequently arise in Hatch-Waxman and other pharmaceutical cases. Many of our team members benefit from the experience of Hatch-Waxman litigation on the brand side. Our team comprises world-class patent litigators and other highly skilled lawyers who possess science degrees in relevant fields, other special skill sets (e.g., IPR and PGR proceedings before the Patent Trial and Appeal Board) and in-house pharmaceutical experience. We have over 20 PhDs, 50 advanced degrees in chemistry, biochemistry, pharmacology and other related life sciences, and 69 registrants with the USPTO. The accumulated knowledge in the relevant science, patent prosecution and patent litigation combined with the real-world experience of in-house work with pharmaceutical companies and their scientists, greatly enhances our ability to formulate creative and strong non-infringement and invalidity positions in Hatch-Waxman cases.

Many of our litigators have knowledge in additional areas of law, such as antitrust and appellate law, which enables us to approach cases from a different perspective and, sometimes, identify issues that otherwise might get overlooked. This team approach gives us the collective experience and technical depth to handle the most challenging matters, and also fosters extraordinary creativity derived from a global viewpoint. Together we solve our clients' most challenging problems.



Bill Long

Atlanta
Washington, DC
D +1 404 527 4170
bill.long@dentons.com



Shalu Maheshwari

Partner
Washington, DC
D +1 202 408 6445
shailendra.maheshwari@dentons.com

Top national rankings in IP Litigation, Patent Litigation and Patent Law, *US News & World Report Best Law Firms in America*

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Clients rank Dentons in the top 10 percent of all law firms for Intellectual Property Litigation, *BTI Litigation Outlook*

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Dentons recognized for IP Litigation and Patent Prosecution, *American Lawyer Media "Go-To Law Firm" for the Top 500 Companies*

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"We have been impressed with their responsiveness and quality of the work." Intellectual Property, *Chambers USA*

Representative matters:

- *Par v. Luitpold* (D.N.J.), Hatch-Waxman case involving epinephrine.
- *The Medicines Company vs. Hospira* (D.Del.): Hatch Waxman litigation involving bivalirudin.
- *APP vs. Hospira* (D.N.J.): Hatch Waxman case involving ropivacaine.
- *Depomed, Inc. v. Ivax Pharmaceuticals* (N.D. Cal.): pharmaceutical patent infringement case involving polymer controlled release delivery systems.
- *CryoLife v. Tenaxis* (N.D. Cal.): patent infringement related-action involving a surgical adhesive manufacturer, under 28 U.S.C. § 1492, in proceedings in the US and Germany.
- *AstraZeneca vs. Impax Laboratories, et al.* (S.D.N.Y.): Hatch-Waxman litigation involving omeprazole.
- *Sanofi-Aventis v. Barr Laboratories* (D.N.J.): Hatch Waxman litigation involving oxaliplatin.
- *Biovail v. Watson Pharmaceuticals* (S.D. Fla.): Hatch-Waxman case involving bupropion hydrobromide products.
- *Shire v. Barr Laboratories* (S.D.N.Y.): Hatch-Waxman case involving lanthanum carbonate.
- Teva Carvedilol cases (D.N.J.): several Hatch-Waxman cases involving carvedilol.
- Depomed v. Actavis and Watson (D.N.J.): Hatch-Waxman case involving diclofenac potassium.
- Brigham & Women's Hospital v. Teva Pharmaceuticals (D. Del.): Hatch-Waxman case involving cinacalcet.
- *Ocular Research of Boston Inc. v. Allergan, Inc.* (E.D. Tex.): Hatch-Waxman case involving prescription eye drops.
- *Amphastar Pharmaceuticals Inc. v. Sanofi-Aventis SA* (C.D. Cal.): False Claims Act Qui Tam action following failed ANDA litigation concerning enoxaparin.
- *Novo Nordisk A/S v. Caraco Pharmaceutical Labs, Ltd.* (E.D. Mich.): Hatch-Waxman case involving Repaglanide-Metformin combination therapy for Type-2 diabetes.
- *Millennium Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al.* (D. Del.), Hatch-Waxman litigation involving MLN341 (bortezomib).
- *Millenium Pharmaceuticals, Inc. v. Sandoz, Inc. et al.* (D. Del.), Hatch-Waxman litigation involving MLN341 (bortezomib).
- *Millenium Pharmaceuticals, Inc. v. Fresenius Kabi USA LLC et al.* (D. Del.), Hatch-Waxman litigation involving MLN341 (bortezomib).
- *Cubist Pharmaceuticals, Inc. v. TEVA Parenteral Medicines, Inc.* (D. Del.), Hatch-Waxman litigation involving Daptomycin.
- Centocor, Inc. v. Genentech, Inc. et al. (C.D. Cal.), patent infringement declaratory judgment action to invalidate a pharmaceutical patent
- *Aventis v. Bristol Myers Squibb*, Hatch-Waxman case involving an oncology drug.
- *TAP v. OWL* (D. Ill.): Hatch-Waxman litigation involving leuprolide.
- *Janssen v. DRL* (D.N.J.): Hatch-Waxman litigation involving risperidone.
- *Sanofi v. DRL* (D.N.J.): Hatch-Waxman litigation involving clopidogrel.
- *AZ v. DRL* (D.N.J.): Hatch-Waxman litigation involving omperazole.
- *Pfizer v. DRL* (D. Ill.) Hatch-Waxman litigation involving amlodapine.
- *Eli Lilly v. DRL* (D.N.J.): Hatch-Waxman litigation involving olanzapine.
- *GSK v. DRL* (D.N.J.): Hatch-Waxman litigation involving ondansetron.