

## Hatch-Waxman Litigation

Rothwell Figg's Hatch-Waxman Litigation practice provides pharmaceutical clients with an unrivaled combination of efficiency, experience, and strategic guidance when dealing with litigation arising under The Drug Price Competition and Patent Term Restoration Act, informally known as the Hatch-Waxman Act. Although we have counseled both brand-name pharmaceutical innovators and generic drug manufacturers, most of our Hatch-Waxman cases involve representing generics.

Typically, generic drugs have to litigate their way into the market by invalidating a patent held by a branded company. We have represented numerous clients in scores of these cases for more than three decades. Trial and appellate litigation under the Hatch-Waxman Act is a significant part of our litigation practice, with several partners engaged in it full-time. These are complex, high-stakes matters involving sophisticated legal and scientific issues.

We bring a unique set of capabilities to our work. The Rothwell Figg Hatch-Waxman team is exceptionally experienced, with deep knowledge of the relevant science. Many of our litigation attorneys have scientific degrees in areas related to pharmaceuticals including chemistry, biochemistry, pharmacy, biology, microbiology, and biotechnology. Our attorneys are seasoned trial lawyers who have handled numerous litigations in popular Hatch-Waxman jurisdictions including the Delaware and New Jersey district courts, as well as less common venues. We routinely litigate Hatch-Waxman cases through trial and on to appeal at the Federal Circuit, but we also provide strategic guidance to reach beneficial settlements where appropriate.

As hands-on litigators, we often provide clients with a realistic, fact-based assessment of the risks and opportunities that they find invaluable. We identify the best strategies to prove non-infringement or invalidity of Orange Book listed patents to give our clients the best odds of winning at trial or successfully settling the case. We have experience in settlement negotiation in these cases and an understanding of the antitrust issues potentially implicated by settlement. This allows us to help our clients avoid antitrust pitfalls, while negotiating the best deals in service to their business goals.

We staff cases leanly and appropriately and are cost-conscious. Our team operates as an integrated, aligned unit, and we are known for our ability to communicate effectively with our clients, both in-house counsel and their management colleagues. We build longstanding working relationships with them that extend over many years. With these clients, we develop a role as a trusted advisor, and a comfortable, informative rhythm of communication and information that suits their needs.

All that notwithstanding, we are litigators. We are aggressive, creative, and tenacious. Our team is smart, extraordinarily hardworking, and handles cases ranging from relatively small matters to very large, complex, multi-party disputes in which we litigate against some of the largest firms in the country. We routinely go toe-to-toe with some of the heavyweights in the industry - and win. We have succeeded in invalidating patents covering multi-billion-dollar drugs or obtaining favorable settlements for our clients. These successes have opened market opportunities for our clients to deliver more affordable generic drugs to the public.

We are well versed in the strategic and practical implications of Hatch-Waxman opportunities. We often work closely with a client's business and strategy team, whether the client has first-to-file status and the potential benefit of a 180-day exclusivity period, or is a later filer that needs to break into the market. Because we are so immersed in the topic, we are able to guide our clients through complex regulatory exclusivity issues to arrive at reliable, successful strategies. And, should those regulatory issues create a need to litigate either for or against the FDA's regulatory decisions, we have years of experience handling temporary restraining order (TRO) or preliminary injunctive proceedings to protect our client's interests.

In big cases, our team is skilled in working closely with other defendants, and their counsel, and do so professionally and effectively. This takes place at all stages of a case, from claim construction to expert discovery to trial. We make sure, always, that our client's interests are protected and that their questions are heard and resolved.

For many of our clients, Hatch-Waxman litigation is the fulcrum of their futures and a critical step in bringing products to market. When so much is at stake, clients rely on our team to develop winning strategies to launch successful generic products as early and as profitably as possible.