haynesboone

HATCH-WAXMAN/ANDA

Practice

PRIMARY CONTACTS

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The Haynes and Boone Hatch-Waxman/ANDA Practice Group is mainly composed of lawyers who have focused in this area for more than two decades. We offer litigation and counseling services to meet each of our client's particular business objectives, not merely the patent issues.

Our lawyers are experienced in the full scope of intellectual property issues related to pharmaceutical development and commercialization, from the initial counseling and pre-suit analysis to litigation under the Hatch-Waxman Act. We routinely handle invalidity, freedom-to-operate, unenforceability, and non-infringement opinions, as well as issues relating to paragraph IV notice letters/detailed statements, § 505(b)(2) applications, skinny labeling, split certifications, API manufacture, at-risk launch, settlement, exclusivity, and forfeiture issues.

Our lawyers have technical backgrounds in scientific fields, which for several team members complements their industry experience. Indeed, many of our practitioners have advanced technical degrees. Thus, our lawyers can evaluate and address the full range of technical and business issues that impact our clients.

Our litigators are experienced in typical ANDA jurisdictions such as Delaware and New Jersey, having frequently litigated under the New Jersey Patent Local Rules, which include unique provisions governing Hatch-Waxman litigation. We also strategically use patent trial proceedings before the United States Patent and Trademark Office's Patent Trial and Appeal Board (PTAB); a practice that requires a unique combination of litigation and technical skills and experience. We are also experienced in litigating cases through final decision on appeal at the U.S. Court of Appeals of the Federal Circuit.

When the situation calls for it, we combine the experience of our ANDA litigation team with that of lawyers in other practice areas, who provide counseling on matters such as financing, antitrust issues regarding settlements or branded pharmaceutical tactics, and appellate procedure and advocacy.

Our goal is to provide each and every client with exceptional service, an unparalleled understanding of the law, and the knowledge and counsel of a trusted advisor familiar with the U.S. pharmaceutical industry, the U.S. patent system, and the overlapping regulatory authority of the FDA in connection with pharmaceutical product launches.