Haug Partners: Leading Experts in Life Sciences

Kaitlin Farrell, Porter Fleming, Nick Giove, Andrew Roper, Andrew Wasson

Hatch-Waxman Litigation – A Proven Track Record of Success with "Brand vs. Generics" Wars

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Will you provide an overview of the Life Sciences practice at Haug Partners?

Haug Partners collaborates with Life Sciences clients to provide comprehensive legal strategies from the inception of an idea through commercialization and next-generation planning. Industry leaders trust and rely on the Firm to help them procure, manage, protect, and maximize the lifecycles of their most valuable intellectual property assets.

Haug Partners has appeared as lead trial counsel in more than 200 Hatch-Waxman litigations in its 25-year history, litigating more than 60 different pharmaceutical products with an overwhelming success rate. Our team includes more than 50 attorneys, mostly with technical degrees who have extensive experience litigating Hatch-Waxman cases as well as biosimilars and biotechnology discoveries. We have also prosecuted over 16,000 issued patents. Haug Partners effectively combines its scientific know-how with extensive trial, FDA, and antitrust experience to achieve optimal results for our life science clients.

What sets Haug's Hatch-Waxman practice apart?

The Firm is a one-stop-shop for Life Sciences clients. From the Hatch-Waxman perspective, this involves extensive expertise not just in protecting our clients' life-saving innovations by maximizing the lifecycles of their pharmaceuticals, but also providing expert insight into related issues including antitrust and FDA. The Firm brings a unique group of exceptionally experienced, bright, diligent, and focused lawyers to a trial who understand the science, are comfortable in the courtroom, versed in the legal and regulatory issues at play, and appreciate the real-world pharmaceutical market dynamics to win and achieve our clients' objectives. Additionally, we are able to tap into our unique history of being an industry-leader in representation of generic pharmaceutical companies before we transitioned to representing on the brand side. All of these factors contribute to the firm's extraordinarily high rate of success in representing Hatch-Waxman plaintiffs.

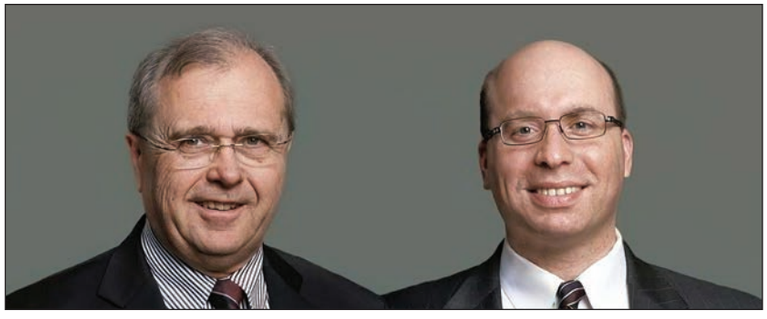
What is the future of the firm's Hatch-Waxman practice?

The Hatch-Waxman practice's future is bright and exciting as the Haug team relies on experienced attorneys and an ever-growing bench of motivated, eager, and capable younger attorneys who participate, contribute and add to a winning team. The practice has evolved into the biosimilars arena, too.

What is something you enjoy about Hatch-Waxman litigation?

We enjoy the opportunity to understand and support the business objectives of our clients both from a high level and also down to the smallest details. We don't just understand the highly technical subject matter behind our clients' hard-earned patents, but we also understand how drugs are formulated and distributed, how doctors prescribe them and how consumers use them. We leverage this knowledge to really "paint a picture" or tell a story for the judge or jury when putting together our strongest case.

Of course, we also enjoy the thrill of achieving favorable results for our clients when the stakes are high. Most recently, the Firm secured a key victory protecting Takeda's multibillion dollar Vyvanse® product from generic competition during the full term of Takeda's patent life. ●



Mike Brockmeyer, David Shotlander

Expertise in Antitrust Litigation and Counseling

Mike Brockmeyer, David Shotlander

How does the Firm's antitrust practice support the firm's mission of enhancing value for technology and life sciences clients?

Our technology and life sciences clients are innovators, and gain value by introducing new and unique products that dominate the marketplace, frequently on account of intellectual property rights. With that success and with IP rights comes antitrust risk, and we routinely work

with these clients to avoid, mitigate and defend against that risk, whether in the initial strategy or throughout the product lifecycle, including at the point of IP enforcement.

What makes the Firm's antitrust practice unique?

Our antitrust practice is unique in two ways. First, we are a small firm practice with a big firm presence. The small firm approach offers us regular access to our patent, regulatory and litigation colleagues, enabling us to better serve our antitrust clients. In the meantime, we take on major complex antitrust cases in roles typically handled by only the largest firms and we counsel on high stakes cutting-edge issues. Second, we are among the leading experts in pharmaceuticals and life sciences antitrust. Beyond working in a lead role on some of the major cases of recent years, we closely follow every development within this space, and we share an understanding of the industry and the law that puts our life science clients at a strategic advantage.

How do you see the antitrust practice evolving?

Our antitrust practice evolves by staying on top of both the technological developments and legal developments that are in constant flux. As products, conduct and theories evolve, our practice moves with them and even subtle changes in the landscape may counsel for change in how we frame certain issues and advise our clients. Likewise, our litigation practice utilizes the best and latest technology, and will continue to evolve as the features and options available to us evolve. ●

Leaders in FDA and Regulatory Affairs

Andrew Wasson

What is your approach to FDA law?

Our approach emphasizes the close relationships that FDA law has with other practice areas in the life sciences sector. FDA regulatory law has a close and important relationship with patent law and litigation between pharmaceutical companies advancing brand products and generic pharmaceutical companies looking to market lower cost drugs. The statutes that authorize generic drugs and follow-on biologics contain extensive provisions relating to the resolution of patent disputes. Issues at the cutting-edge of FDA regulatory law also underpin many antitrust disputes in the pharmaceuticals sector. Appreciating the many touch points between the areas of law is not only intellectually challenging, but it provides a richer approach to litigation and product strategy.

How does FDA law effect patent litigation in therapeutics?

FDA regulatory statutes have many direct effects on patent litigation in pharmaceuticals and biologics. For one, regulatory exclusivities can affect the timing of when a patent litigation can start. The statutes that govern generic or follow-on therapeutics often prescribe exclusivities that limit when a generic or follow-on applicant can file an application with the Agency. For drugs that are new chemical entities and for biological products, the relevant statutes prevent a generic applicant from even filing an application until four years from the approval of the innovator product. And then relevant statutes contain provisions that give rise to other types of exclusivities as well, which govern when the FDA can approve a generic product (e.g. orphan drug exclusivity, clinical exclusivities, and pediatric exclusivity).

What is the relationship between FDA law and antitrust litigation?

FDA regulatory law is also sometimes implicated in antitrust disputes in the pharmaceuticals sector and our regulatory practice often supports our antitrust colleagues. For instance, antitrust plaintiffs sometimes allege that innovator pharmaceutical companies improperly petitioned the FDA to institute inappropriate requirements on generic competitors. Understanding whether arguments are reasonable often has antitrust implications and requires deep experience with Agency precedent.

What are some other issues at the intersection of FDA law and patent law?

One major area where FDA and patents overlap is the FDA publication colloquially called the Orange Book – the print edition many years ago had an orange cover. The types of patents that can – and should not – be listed in the Orange Book can have wide-ranging repercussions. For instance, generic applicants have to take a position on the infringement and validity of patents listed in the Orange Book, which could give rise to a 30-month litigation stay during which the FDA generally cannot approve a generic applicant. Knowing the line between "listable" and "unlistable" patents requires judgment and familiarity with a decades long dialogue between the Agency, industry, and lawmakers.

What are some ways that high tech advances are transforming FDA law?

Advances in computer science are transforming every industry, including pharmaceuticals. As the pharmaceutical industry continues to harness new computing advances, the FDA faces the increasing challenge of determining whether, and to what extent, regulation applies to these new uses. However, these challenges are not new to the Agency – the FDA has been addressing the growing number of medical devices incorporating AI and machine-learning for a number of years. ●

Trusted Representation at the USPTO

Brian Murphy

Brian Murphy

How does your experience as a former Lead Administrative Patent Judge shape your practice?

The Patent Trial and Appeal Board (PTAB) is a high-profile business unit of the U.S. Patent & Trademark Office responsible for taking a second look at commercially important patents. For example, a company sued for patent infringement in federal district court can now challenge the validity of the asserted patent in a PTAB proceeding that is much faster and less expensive than district court patent litigation. I served as a PTAB judge for four years, including three years on the leadership team where I was a Lead Administrative Patent Judge responsible for supervising, training, and mentoring a team of 15 Administrative Patent Judges. I also presided over nearly 200 PTAB patent validity challenges that impacted some of the most successful companies in the world – AstraZeneca, Apple, AT&T, Baxter Healthcare, Cox Communications, Eli Lilly, Google, Lenovo, Microsoft, and 3M Company, among others.

My experience allows me to provide clients with strategic and tactical advice in PTAB patent validity proceedings as a critical component of an integrated patent litigation strategy. In particular, I help identify, distill, and forcefully present the most relevant and material evidence of record in our briefs and at oral argument. I often conduct mock PTAB and Federal Circuit arguments to help prepare lead counsel to be most effective at oral argument. On occasion, I also serve as an expert witness in patent practice and procedure.

How does the PTAB practice contribute to Haug Partners' mission of maximizing the value of its clients' patent portfolios?

Haug Partners has a very successful track record when defending patent owners in PTAB patent validity trials. PTAB cases we have handled range across many technology disciplines: pharmaceuticals, biotechnology, biomedical devices, mechanical and electrical devices, and related computer science and software. Our firm grasp of legal, scientific, and procedural nuances yields critical insights when litigating complex patent cases, which is key to our effective representation of innovative life sciences and technology clients at the PTAB. Haug Partners attorneys are well prepared and adept at explaining the legal and technical positions crucial to persuasive argument before technically savvy PTAB judges.

I bring the cold eye of an experienced judge and passion of a long-time trial advocate to advance each client's interest in every case. In virtually all completed cases where Haug Partners has defended a patent owner in PTAB patent validity challenges, the firm has either won a denial of the patent challenger's petition, a Final Written Decision upholding the patent claims, or a favorable settlement. Clients trust our PTAB expertise. ●