Pharma and Biotech Patents: A Hatch-Waxman and BPCIA (Biosimilars) Immersion Course Encompassing Prosecution Strategies, FDA Regulation, Post-Grant Challenge, and Litigation

- **Dates:** April 10-12, 2019
- **Venue:** Hyatt Regency Sarasota, Florida
- **Schedule:** 8:15-11:30; 1:00-3:45 (Wed-Fri)
- **Projected CLE Credit:** 16.5
- **Faculty:** Janis Fraser; Geoff Biegler; Terry Mahn; Dorothy Whelan (Fish & Richardson)

This course will let you hone the skills needed to prosecute, evaluate, challenge, and enforce pharmaceutical and biotech claims in an ever-changing legal and economic climate. Learn cutting-edge strategies for putting pharmaceutical and biotech patents, US regulatory law and dispute resolution techniques to work for your company's benefit. This “immersion” course is taught by an experienced team who puts it all together for you. It will be valuable not only for attorneys but also for any corporate decision maker who needs to understand how the Hatch-Waxman and biosimilars legislation shape complex patent and regulatory decisions for his or her company.

The course starts with a broad survey of the Hatch-Waxman and BPCIA legislation provisions that underpin the strategies to be discussed throughout the course. The course then conveys both fundamentals and advanced legal strategies in three major areas: (1) pharmaceutical and biotech patent prosecution; (2) litigation and appeal; and (3) post-grant challenges such as inter partes review and post-grant review. These topics are taught as a seamless whole by four principals from Fish & Richardson P.C., who utilize frequent cross-references to highlight the interplay among all the topics. For example, relevant patent case law (including the most recent biotech and pharma cases) is discussed from different viewpoints in the context of prosecution and enforcement. An expert on the Hatch-Waxman and biosimilars laws will provide a coherent overview of these complex provisions; another lecturer will explain these laws’ critical importance to patent enforcement in the pharmaceutical and biotech fields; and others will show how these laws inform strategy in prosecution and post-grant challenges. Strategies for managing the life cycle of patented drugs is a theme that echoes throughout the course.

This course provides valuable, practical information for the patent practitioner, whether in-house or in private practice, to use in maximizing protection of biotechnology and pharmaceutical inventions with an eye to possible future enforcement and post-grant validity challenges. The litigator will come away with a comprehensive understanding of the pertinent case law and concepts necessary to enforce pharmaceutical and biotechnology patents, to recognize the weaknesses in improvidently granted patents, and to weigh strategic considerations. Company executives tasked with making strategic decisions based on their own company’s patent portfolio as well as those of their competitors will benefit immeasurably from the broad understanding of biotech and pharmaceutical patent and Hatch-Waxman law gleaned from this immersion course.