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BIOSIMILARS

Practice

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The Haynes and Boone Biosimilars Practice Group offers litigation and counseling services to clients in the biotechnology industry, in particular, to clients developing and/or marketing biosimilar drug products. The Biosimilars Practice Group is a natural extension of the firm's Hatch-Waxman Practice Group, which is experienced in representing clients in all aspects of the generic pharmaceutical business.

Our lawyers understand the full scope of intellectual property issues related to the emerging field of biosimilar development and commercialization, from initial counseling and pre-suit analysis to litigation under the Biologics Price Competition and Innovation Act ("BPCIA"). Our lawyers have technical backgrounds and industry experience in relevant scientific fields. Indeed, many of our practitioners have advanced technical degrees, and several have doctoral degrees, in such fields as biochemistry, organic chemistry, and microbiology and molecular genetics. The scientific capabilities of our lawyers enables them to fully understand the technical and scientific issues facing our clients in the biosimilar industry so that we can rigorously evaluate and address the full range of issues involved in any particular matter.

Our litigators have extensive experience litigating in the pharmaceutical space. Our litigators were involved in one of the first litigations involving a protein (*Evans Medical Ltd. v. American Cyanamid Co*., 215 F.3d 1347 (Fed. Cir. 1999)). Our litigators are also highly-skilled in litigating cases through appellate decision at the U.S. Court of Appeals of the Federal Circuit. When necessary, we combine the experience of our 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.

Where appropriate, we 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. Our firm has extensive experience practicing before the PTAB.

Our years of experience in pharmaceutical matters, our strong technical/scientific experience, and our knowledge and understanding of the patent and regulatory laws position our team to address the most complex and challenging intellectual property issues facing our clients in the biosimilar industry.

Our goal is to meet each of our client's particular business objectives by providing exceptional service coupled with an unparalleled understanding of the law, scientific and technical issues, the U.S. patent system, and the regulatory requirements of the U.S. Food & Drug Administration.

Selected Non-Confidential Experience:

- *Cellectis S.A. v. Precision Biosciences Inc.*, 937 F.Supp.2d 474 (D. Del. 2013) (recombinant DNA technology).
- *Novo Nordisk Pharmaceuticals, Inc. et al. v. Bio-Technology General Corp. and Teva Pharmaceuticals USA, Inc.*, 424 F.3d 1347 (Fed. Cir. 2005) (recombinantly produced human growth hormone).
- *Evans Medical Ltd. v. American Cyanamid Co.*, 215 F.3d 1347 (Fed. Cir. 1999) (purified protein/antigen technology).