Rothwell Figg Launches Blog Dedicated to Biologics and Biosimilars

Firm News
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Rothwell Figg is proud to introduce its new blog, BiosimilarsIP.com. The blog features articles, updates, and analysis on regulatory issues, legal decisions, and other news related to biologics and biosimilars under the Biologics Price Competition and Innovation Act (BPCIA). The posts, authored and edited by attorneys in the firm's Biologics and Biosimilars practice, track regulatory issues and events, provide analysis of legal decisions from federal courts and from the Patent Trial and Appeal Board (PTAB), and offer updates on current news and events related to biologics and biosimilars.

The BPCIA established an abbreviated pathway for licensure of biological products determined by FDA to be biosimilar or interchangeable with an FDA-approved reference product. The FDA defines a biosimilar as a biological product that is shown to be highly similar to the reference product for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. To be considered interchangeable, product must be biosimilar to the reference product and must also meet additional requirements demonstrating that the product is expected to produce the same clinical results as the reference product in any given patient. Although the goal of the BPCIA is conceptually similar to that of Hatch-Waxman, biosimilars are not generic version of the reference product. Biologics are much larger and much more complex than small molecule pharmaceuticals.

Rothwell Figg understands the manufacturing, regulatory, and legal requirements for biologics and biosimilars, and we put our IP experience to work for our clients. We have the experience and the technical knowledge required to develop a successful IP strategy for the most sophisticated biologic and biosimilar matters, including issues related to regulatory approval, securing patent rights, counseling and opinions, post-grant challenges, and asserting or defending against patents in litigation.

Our clients benefit from the depth and breadth of our 30-plus year of experience in complex biotech areas including gene cloning/genetic engineering, monoclonal antibodies, chimeric/humanized antibodies, proteomics, recombinant DNA, siRNA, viral replications, receptor technology and cell signaling, molecular diagnostics, and other research tools. We have extensive experience litigating in life sciences. Our attorneys are also experienced in litigation involving the FDA under the APA, and all other areas of IP litigation. We also have extensive experience with post-grant proceedings, counseling and opinions, and patent prosecution, including international involvement. In addition, many of our lawyers have first-hand industry experience, and many have advanced degrees in areas such as microbiology, genetics, biochemistry, bioinformatics, chemistry, biotechnology, pharmacy, biology, zoology, and other scientific fields.

Please visit our Biologics and Biosimilars blog, and sign up for updates using the 'Sign Up for Updates' section on the right side.

To visit the firm's PTAB blog, providing updates, articles, and analyses on the PTAB, the Court of Appeals for the Federal Circuit, and the America Invents Act (AIA), please click here.