Biologics and Biosimilars

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The Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama on March 23, 2010, amended the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are demonstrated to be “biosimilar” to or “interchangeable” with an FDA-licensed biological product. This pathway is provided in the part of the law known as the Biologics Price Competition and Innovation Act (BPCI Act). Under the BPCI Act, a biological product may be demonstrated to be “biosimilar” if data show that, among other things, the product is “highly similar” to an already-approved biological product. In addition, this pathway sets forth guidelines for the production, use, and sale of these “biosimilars” or “follow-on” biologic therapeutics in the U.S.

The abbreviated pathway comes a quarter century after passage of the Hatch-Waxman Act, which provides an abbreviated pathway in the U.S. for generic drugs (i.e., synthetic chemical entities and small molecule drugs). The U.S. Food and Drug Administration will likely look to the European Medicines Agency, which passed an analogous legislation in 2003, for guidance regarding biosimilars approvals.

Look to Kilpatrick Townsend to advise you regarding biologics and biosimilars. Kilpatrick Townsend counsels with respect to litigating intellectual property issues relating to reference and follow-on biologics, including the abbreviated regulatory pathway for biosimilars. Our attorneys’ legal and technical expertise enables Kilpatrick Townsend to provide valuable insights into the subtleties and complexities necessary to navigate this new and developing area of law and create and grow new business opportunities.