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The role of patents in biosimilars and biobetters

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The Biologics Price Competition and Innovation Act (BPCIA) provide an approval pathway for biosimilar products. Within the BPCIA, there is twelve year exclusivity for the originator/reference product. Whereby, the Food and Drug Administration (FDA) will not approve a biosimilar application until 12 years after the approval of the reference product. Although the BPCIA provides a patent litigation scheme to determine infringement by the time of the biosimilar approval, it may not be necessary since the 12 year exclusivity may outlast the patent term, even with patent term extension. However, the twelve year exclusivity does not render biologic patents obsolete. Originator molecules are not afforded any exclusivity from non-biosimilar molecules, e.g., Biobetters. Since the definition of a biosimilar (a highly similar molecule) is still being defined by the FDA, and may also continue to evolve with time, variations to the originator molecule may or may not be encompassed by the BPCIA exclusivity period. This session will evaluate what is and is not protected under the current regulatory pathway and the patent landscape.

Biography

Brian R. Dorn, Ph.D., is a patent attorney at Barnes & Thornburg LLP's Minneapolis office. Dorn has an array of experience in intellectual property with particular emphasis on biotech, pharmaceutical and medical device patent prosecution and opinion work. Dorn's practice also includes international patenting, where he works with universities, companies, and patent attorneys outside the United States to obtain patents in and outside the United States. Dorn earned his J.D. magna cum laude and his Ph.D. from the University of Florida Colleges of Law and Medicine, respectively, in 2003. Full biography at http://www.btlaw.com/brian-r-dorn/

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