Insights: Publications

The Biologics Price Competition and Innovation Act: Is a Generic Market for Biologics Attainable?

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The Biologics Price Competition and Innovation Act of 2009 (BPCIA) provides an abbreviated approval pathway for biological therapeutic products shown to be biosimilar to an FDA-approved biological reference product. The BPCIA purported to reduce the price of biologics while promoting innovation. In two recent cases, the Federal Circuit interpreted a key provision of the BPCIA requiring an applicant to provide the reference product sponsor with notice 180 days before marketing the product. The Federal Circuit's interpretation extends the exclusivity period already provided for the reference product sponsor, deterring innovation and price reduction. Thus, the Supreme Court granted certiorari in one of the cases.