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Biologics Price Competition & Innovation Act (BPCIA): Litigation Considerations

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A Practice Note discussing strategic considerations when litigating a biosimilars case under the Biologics Price Competition & Innovation Act (BPCIA). It explains biologics, discusses the history and intent behind the BPCIA, the Food & Drug Administration's (FDA)'s Purple Book, biosimilar FDA regulatory approval and exclusivities, strategic pre-litigation and litigation considerations for both reference product sponsors and biosimilar applicants, and antitrust considerations in BPCIA settlements.

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