10 KEY TAKEAWAYS

Navigating Litigation Under the Biologics Price Competition and Innovation Act BPCIA

On January 11, 2024, **Kilpatrick** Partner **April Isaacson** and Counsel **Yifan Mao** presented "Navigating Litigation Under the Biologics Price Competition and Innovation Act (BPCIA)" to entrepreneurs in the Chinese life science community over Intellectual Property (IP) ForeFront, a media platform focusing on original interpretations of policy intellectual property, case analysis, and cutting-edge trends in the field of intellectual property. About 280 in-house counsels attended the online event. Mss. Isaacson and Mao discussed the history and intent of the BPCIA, the 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.

Five takeaways for Reference Product Sponsor (RPS) litigants:

1. Strategically assess and develop a patent portfolio comprising a variety of patent claims that can be used in BPCIA litigation.
2. Evaluate the strengths of each patent to withstand validity challenges through both federal district court infringement litigation and IPR proceedings.
3. Create an internal Purple Book listing, including expiration dates, PTAs and potential PTEs.
4. If the Reference Product (RP) is covered by exclusively licensed third-party patents, review the notice provisions, licensee obligations, licensor obligations and any confidentiality issues that may be raised by Purple Book listing.
5. Designate a point person with comprehensive knowledge of the inventive story and patent positions to manage the BPCIA litigation.

Five takeaways for Biosimilar Applicants litigants:

1. Perform FTO and landscape searches for patents owed by or licensed to the RPS and identify potential design-around options for process claims.
2. Assess the strengths and weaknesses of invalidity, enforceability, and non-infringement positions.
3. Seek exclusivity for a first-approved interchangeable product.
4. Produce all information required by the FDA for approval ahead of competitors in order to be first to market.
5. Strategically assess and develop a patent portfolio comprising a variety of patent claims that can be used in BPCIA litigation.

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