Axinn Partner Pens Article on Biosimilar Approval Standards Under BPCI

June 2, 2011

ATTORNEYS

Landmon, Chad

PRACTICE AREAS

Intellectual Property

In a Pharmaceutical Technology article written by Axinn Partner Chad Landmon discussed the developing industry of biosimilar products. Landmon focused on the U.S. Food and Drug Administration's current efforts to weigh opposing views of biosimilars under the Biologics Price Competition and Innovation Act. He presented the contrasting views of innovators and biosimilar proponents and focused on issues of exclusivity, interchangeability, biosimilarity standards and FDA published guidelines. "At least initially, FDA is likely to adopt a product-specific model, with requirements varying from product-to-product," Landmon wrote. "The companies that will be successful in launching the first biosimilar products will be those who advocate effectively in relation to the FDA's requirements." No matter what policies the FDA sets, he concluded, disputes and court actions will likely surface over approval requirements for biosimilars.

The article, titled "Advocating for Biosimilar Approval Standards Under BPCI," was published by Pharmaceutical Technology on June 2, 2011 in Volume 35, Issue 6, pp. 81-82.