

Events

November 09, 2021

ACI 16th Annual Paragraph IV Disputes Conference



Perkins Coie sponsored the [ACI 16th Annual Paragraph IV Disputes Conference](#) which was held November 9 - 10 in New York.

Partner David Anstaett, along with others, presented on "Written Description and Enablement: Defensive Strategies and Offensive Moves for §112 Rejections and Attacks" on November 10.

11.10.2021

Written Description and Enablement: Defensive Strategies and Offensive Moves for §112 Rejections and Attacks

In one of the most important patent stories of the year, the Federal Circuit issued a groundbreaking decision concerning the validity of antibody epitome claims covering a reference product. In *Amgen Inc. v. Sanofi*, No. 20-1074 (Fed. Cir. 2021), the court held that "a genus of antibodies claimed only by specific functional properties are invalid for lack of enablement." The Federal Circuit invalidated all claims for lack of enablement, holding that "the binding limitation itself was sufficient for the claims to require undue experimentation." In view of this precedential decision, this panel will consider the new requirements for creating a valid patent and how best to leverage recent decisions.

- Identifying best practices for meeting the written description and enablement requirements
 - How to survive invalidity and unpatentability challenges
- Evaluating the enablement and written description of claims directed to a genus of antibodies
- Examining the Federal Circuit's recent approach and interpretation of written description under §112 as it applies to small molecules
- Assessing current patents for written description vulnerabilities under these Federal Circuit opinions
- Examining patent challenges and defenses in ANDA proceedings under this new §112 jurisprudence

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