

7 KEY TAKEAWAYS

Key Takeaways: The Federal Circuit's New § 112 Attack on Biotechnology: Diagnosis and Prescription

Kilpatrick attorneys [Yifan Mao](#) and [Stuart Pollack](#) recently attended the 20th annual KTIPS (Kilpatrick Townsend Intellectual Property Seminar) to discuss the **"The Federal Circuit's New § 112 Attack on Biotechnology: Diagnosis and Prescription."** The recent rulings from the Federal Circuit have emphasized the importance of the written description and enablement defenses in patent litigation and prosecution, particularly in the field of biotechnology. This new case law now requires that inventors provide a detailed process for identifying new antibodies, peptides, proteins, and nucleic acids that may be discovered in the future and providing structural information for these bioproducts. This session described the new law, discussed the implications and suggested effective approaches to counter these defenses during patent prosecution.

Yifan and Stuart provide these key takeaways from their presentation:

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The courts now apply new tests for the written description and enablement requirements.

The written description requirement now requires a patent owner to produce evidence supporting any one of a representative-species test; a structure-function test; or a common-structural features test.

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The enablement requirement now requires a patent owner to produce evidence showing either (a) that no substantial time and effort would be required to cumulatively identify and make all or almost all possible embodiments that might satisfy the claims; or (b) that there is a quality common to every functional embodiment.

To meet the representative species test, a patent owner can use means-plus-function claiming, incorporate prior art by reference if it contains representative species, or provide prophetic and real examples.

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To meet the structure-function test, the patent owner can incorporate information regarding the relationship between structure and function for chemicals, ligands, agonists and antagonists, enzymes, and nucleic acids and describe the secondary structure of proteins and their roles. Description requirement similarly apply to the two similar tests now required to show enablement.

To meet the common-structural features test, the patent owner can describe common structural features among chemicals, proteins, and nucleic acids and use mean-plus-function claiming.

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These prescriptive recommendations for meeting the written description requirement similarly apply to the two tests now required to show enablement.

For more information, please contact:

www.ktslaw.com

Yifan Mao, ymao@ktslaw.com

Stuart Pollack, spollack@ktslaw.com