

Insights: Publications

Drug Discovery Catch-22: A Healthy Dose of Written Description

Kilpatrick Townsend MEMO|Biopharma Industry Blog

February 8, 2022

Written by **Yifan Mao**

To satisfy the written description requirement under 35 U.S.C. 112, a patent specification must describe the claimed invention in such sufficient detail that a person of skilled in the art (POSA) can reasonably conclude that the inventor had possession of the claimed invention. In *Biogen International GmbH v. Mylan Pharmaceuticals Inc.*, at issue is whether the specification provides adequate written description for method of use claims to a specific dosage strength, 480 mg/day, of dimethyl fumarate (DMF480). On November 30, 2021, in a split decision, the Federal Circuit affirmed the district court decision finding the method claims of the '514 patent invalid for lack of written description.

Related People



Yifan Mao

t 650.324.6311

ymao@ktslaw.com