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Patent case: Biogen International GmbH v. Mylan Pharmaceuticals Inc., USA

Kevin M. Finson (Wolters Kluwer Legal & Regulatory US) · Thursday, December 30th, 2021

A person of ordinary skill in the art could not determine the effective dose of the active ingredient in Tecfidera from the original patent specification.

A West Virginia federal district court's decision that certain claims of a Biogen patent directed to the multiple sclerosis treatment drug Tecfidera were invalid for lack of written description support was not clearly erroneous, the U.S. Court of Appeals for the Federal Circuit has held. The original specification did not give a person of ordinary skill in the art any reason to believe that the particular dosage of dimethyl fumarate claimed was effective. Circuit Judge O'Malley filed a dissenting opinion (Biogen International GmbH v. Mylan Pharmaceuticals Inc., November 30, 2021, Reyna, J.).

Case date: 30 November 2021

Case number: No. 20-1933

Court: United States Court of Appeals, Federal Circuit

A full summary of this case has been published on [Kluwer IP Law](#).

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