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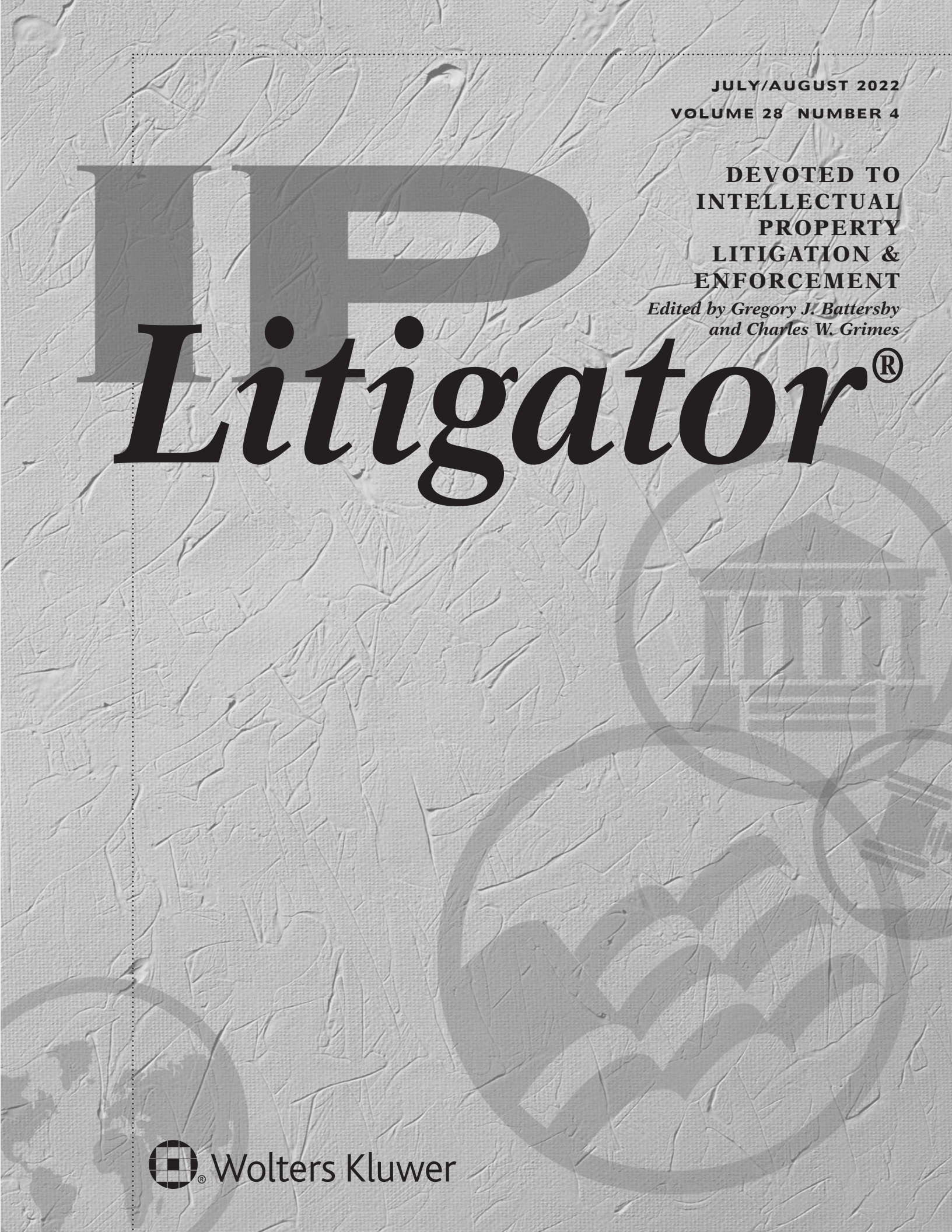

Wolters Kluwer

Pharmaceutical Litigation

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Rehearing Denied in Federal Circuit's Ruling Against Tecfidera® Patent for Lack of Written Description

On March 16, 2022, the Federal Circuit denied Biogen's petition for rehearing of its November 2021 decision in *Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 18 F.4th 1333, 1343 (Fed. Cir. 2021), which found that Biogen's patent U.S. 8,399,514 ("the '514 patent") covering the treatment of multiple sclerosis (MS) with dimethyl fumarate (DMF, Brand name Tecfidera®) invalid for lack of written description.

Facts of the Case

The core issue in the panel's 2-1 decision in November 2021 was whether the specification of the '514 patent sufficiently supported the claimed therapeutically effective DMF dose 480 mg per day (DMF480) in MS treatment. The panel majority found that the DMF480 dose was disclosed only once in the specification and only appeared at the end of a dose range among a series of ranges and held that the specification's focus on basic research and the mere disclosure of broad dosage ranges showed that the inventors did not possess the therapeutically effective DMF480 dose at the time of filing the application. The panel majority asserted that what matters in this case is whether "a skilled artisan could deduce simply from reading the specification that DMF480 would be a therapeutically effective treatment for MS." *Biogen* at 1344.

In dissent, Judge O'Malley cited Biogen's explanation that while clinical efficacy would require a showing of superior clinical endpoints compared to the standard care of MS, therapeutic efficacy refers to the drug dose that can prevent, delay onset of, or ameliorate symptom of MS. Judge O'Malley argued that the majority erred by conflating therapeutic efficacy and clinical efficacy, and by requiring the patent specification to show clinical efficacy to satisfy its heightened written description test. In Judge O'Malley's view, where only therapeutic efficacy should be sufficient. Indeed, Judge O'Malley succinctly summarized the problem created by the district court and propagated by the majority, *i.e.*, "after acknowledging that clinical data demonstrating effectiveness is not required to satisfy written description, the district court went on to find that the '514 patent does not demonstrate possession because it lacks clinical efficacy data." *Id* at 1349.

Higher Standard For Written Description Requirement?

In its rehearing petition, Biogen argued that the panel's decision created a higher standard of written description by requiring (a) the proof of the efficacy rather than the disclosure of the claimed method and (b) the specification repeatedly describing and singling out the claimed drug dose. Biogen's petition was supported by amicus briefs filed by various pharmaceutical groups including The Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and the American Chemical Society.

Judge Lourie, joined by Judges Moore and Newman, dissented from the court's denial of rehearing the case. Judge Lourie reviewed various precedential cases where the Federal Circuit had found lack of written description, but asserted that "this case, in which every claim limitation is expressly described in the disclosure of the patent specification, is at the farthest end of the spectrum of cases where written description has not been found. It is an outlier."

Judge Lourie argued that there are four grounds of errors in the panel majority's decision that the *en banc* court should have corrected. For the first ground, he argued that one mention in the specification is enough to support a claim element, but the panel majority overly emphasized unclaimed disclosures in the specification and did "irrelevant comparisons between the amount of disclosure of the claimed subject matter versus the unclaimed subject matter." On the second ground, Judge Lourie pointed out that the specification expressly states the DMF480 dose and argued that the Federal Circuit precedent does not require the specification to prove the efficacy of the claimed pharmaceutical composition, which would be the province of the FDA. The third ground in Judge Lourie's dissent is that the panel majority's decision had imported "extraneous legal considerations into the written description analysis," including enablement and best mode

requirements, and "create[d] confusion…regarding what is required to meet the written description requirement. Regarding the last ground, Judge Lourie argued that the panel majority's consideration of extrinsic evidence is improper because "extrinsic evidence should be used only as part of an objective inquiry into what is meant by the disclosure in the patent specification," but "[m]eaning is not in question in this case."

The majority's opinion appears to set a higher standard for written description requirement at least for claims directed to therapeutic methods. However, in a recent decision *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1370 (Fed. Cir. 2022), the Federal Circuit found that a claim element "absent an immediately preceding loading dose regimen," which was nowhere disclosed in the specification, satisfied the written description requirement. These decisions can be difficult to reconcile. Also, in view of the vigorous dissenting opinions discussed above, this case may be headed to the Supreme Court. We will keep monitoring this case and report on future developments.

Dr. Xiaoban Xin is a patent attorney at Rothwell Figg. With years of experience as a biomedical researcher, Dr. Xin assists companies and research institutes with building, managing, and protecting their patent assets, strategic patent counseling, and due diligence. Xiaoban has specific experience working with clients in the fields of biotechnology, including gene editing (e.g., CRISPR technology), next generation sequencing, immunotherapy, cell therapy, biologics, stem cells, genetically modified animals, and pharmaceutical formulations, as well as medical device and health IT.