

No. 21-

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IN THE  
**Supreme Court of the United States**

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BIOGEN INTERNATIONAL GMBH AND BIOGEN MA INC.,  
*Petitioners,*

*v.*

MYLAN PHARMACEUTICALS INC.,  
*Respondent.*

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ON PETITION FOR A WRIT OF CERTIORARI TO THE  
UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT

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**PETITION FOR A WRIT OF CERTIORARI**

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## QUESTION PRESENTED

Biogen's asserted patent, which claims methods of treating multiple sclerosis by orally administering 480 mg/day of dimethyl fumarate (DMF), expressly states that "an effective dose of DMF ... to be administered to a subject orally can be from ... about 480 mg to about 720 mg per day." Over a dissent from the panel decision and the dissent of three additional judges from the denial of rehearing en banc, the Federal Circuit nonetheless held that Biogen's patent did not satisfy 35 U.S.C. § 112's requirement to provide a "written description of the invention" because the patent's description of the claimed dose did not include data proving the 480 mg/day dose's efficacy, the claimed effective dose was "listed only once" in the specification, and the patent disclosed other inventions as well.

The question presented is:

Is 35 U.S.C. § 112's requirement that a patent specification "contain a written description of the invention" met when the specification describes the invention, or must the specification also disclose data that demonstrates the claimed invention is "effective" and emphasize the claimed invention by singling it out and describing it more than once?

(i)

## **CORPORATE DISCLOSURE STATEMENT**

Petitioners Biogen International GmbH and Biogen MA Inc. (collectively “Biogen”) are owned directly, or indirectly, by Biogen Inc. No other publicly held company owns 10% or more of Petitioners’ stock.

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