IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

MERCK SHARP & DOHME CORP., *Plaintiff*, v. MYLAN PHARMACEUTICALS INC., *Defendant*.	Civil Action No. 19-cv-101 (IMK)

MERCK'S RESPONSE TO
MYLAN'S NOTICE OF SUPPLEMENTAL AUTHORITY

The cited Federal Circuit decision, *Novartis Pharmaceuticals v. Accord Healthcare Inc.*, Case No. 21-1070 (June 21, 2022), has no bearing on this case. Mylan emphasizes that the majority and dissent agree that, to satisfy the written description requirement, the specification must convey that the inventors had possession of the claimed invention as of the filing date, as if that were somehow in dispute here. Merck, of course, agrees with that hornbook proposition. As explained in Merck's Responsive Post-Trial Brief (D.I. 176) on pages 34-35, the '708 patent contains an explicit disclosure of the claimed 1:1 DHP salt of sitagliptin, including "a hydrate thereof," thereby demonstrating possession. *Id.* (citing *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 730-31 (Fed. Cir. 2014) (holding, on similar facts, that a claim to a compound or "a pharmaceutically acceptable solvate thereof" had written description support)).[1]

[1] *Novartis* involved the absence of support for a "negative limitation" in a method of treatment claim. None of the asserted claims here include such a limitation.

Dated: June 23, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

Undersigned counsel certifies that on June 23, 2022, *MERCK'S RESPONSE TO MYLAN'S NOTICE OF SUPPLEMENTAL AUTHORITY* was served upon counsel of record through CM/ECF.

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