

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner

Case No. IPR2018-01675
U.S. Patent No. 8,603,044

PATENT OWNER'S RESPONSE

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Cases

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<i>Williamson v. Citrix Online, LLC</i> , 792 F.3d 1339 (Fed. Cir. 2015)	11, 13

Other Authorities

37 C.F.R. § 42.6(a)(3)	29
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