UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC, Petitioner,

v.

BIOGEN MA INC., Patent Owner.

Case IPR2015-01136 Patent 8,399,514 B2

BIOGEN'S PRELIMINARY RESPONSE



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TABLE OF AUTHORITIES

Cases	age(s)
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Cisco Sys., Inc. v. Constellation Techs. L.L.C., IPR2014-01085, Paper 11 (PTAB Jan. 9, 2015)	20
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Google Inc. v. B.E. Tech., L.L.C., IPR2014-00038, Paper 9 (PTAB Apr. 9, 2014)
Graham v. John Deere Co. of Kansas City, 383 U.S. 1 (1966)
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Johnston v. IVAC Corp., 885 F.2d 1574 (Fed. Cir. 1989)
Kinetic Techs., Inc. v. Skywork Solutions, Inc., IPR 2014-00529, Paper 8 (PTAB Sept. 23, 2014)10
Knoll Pharm. Co. v. Teva Pharm. USA, Inc., 367 F.3d 1381 (Fed. Cir. 2004)
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