

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEALS BOARD

AMNEAL PHARMACEUTICALS LLC
Petitioner

v.

HOSPIRA, INC
Patent Owner

Inter Partes Review No. IPR2016-01578
Patent 8,338,470

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,338,470

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TABLE OF AUTHORITIES

Cases

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<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966)	14
<i>Hospira Inc. v. Ben Venue Laboratories, Inc.</i> , No. 14-cv-01008 (D. Del. filed August 1, 2014)	28
<i>Hospira, Inc. et al. v. Ben Venue Laboratories, et al.</i> No. 14-cv-00487 (D. Del. filed April 18, 2014)	28
<i>KSR Int'l Co. v. Teleflex, Inc.</i> , 550 U.S. 398 (2007)	14, 40, 46
<i>Microsoft Corp. v. Proxyconn, Inc.</i> , 789 F.3d 1292 (Fed. Cir. 2015)	11
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).....	11

Statutes

35 U.S.C. § 102(b)	15, 16, 17
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Other Authorities

M.P.E.P. § 708.02	7
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