On behalf of: Par Pharmaceutical, Inc.

Entered: August 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.

Petitioner

v.

NOVARTIS AG
Patent Owner

Case IPR2016-01479 U.S. Patent No. 9,006,224

Before LORA M. GREEN, CHRISTOPHER L. CRUMBLEY, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PETITIONER'S REPLY



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TABLE OF AUTHORITIES

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CASES	
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Allergan, Inc. v. Apotex Inc., 754 F.3d 952 (Fed. Cir. 2014)	14, 15
Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc., 752 F.3d 967 (Fed. Cir. 2014)	22
CSS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359 (Fed. Cir. 2002)	3
Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993)	21
Genzyme Therapeutic Prods. L.P. v. Biomarin Pharm. Inc., 825 F.3d 1360 (Fed. Cir. 2016)	15
In re Mouttet, 686 F.3d 1322 (Fed. Cir. 2012)	8
<i>In re O'Farrell</i> , 853 F.2d 894 (Fed. Cir. 1988)	13
Merck & Cie v. Gnosis SpA, 808 F.3d 829 (Fed. Cir 2015)	23
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Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299 (Fed. Cir. 2006)	24
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PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342 (Fed. Cir. 2007)	9, 10
Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005)	3
SEB S.A. v. Montgomery Ward & Co., 594 F.3d 1360 (Fed. Cir. 2010)	3
Smith & Nephew, Inc. v. Rea, 721 F.3d 1371 (Fed. Cir. 2013)	8
Toro Co. v. MTD Prods. Inc., IPR2016-00219, Paper 39 (P.T.A.B May 10, 2017)	3
OTHER AUTHORITIES	
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