UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLAXOSMITHKLINE CONSUMER HEALTHCARE HOLDINGS (US), LLC, Petitioner,

v.

CIPLA LTD.,

Patent Owner.

Case IPR2020-00371

Patent No. 9,901,585

PATENT OWNER PRELIMINARY RESPONSE



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TABLE OF AUTHORITIES

CASES

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Akzo N.V. v. USITC, 808 F.2d 1471 (Fed. Cir. 1986)4	4
Anglefix, LLC v. Wright Med. Tech., Inc., No. 13-2407, 2015 WL 9581865 (W.D. Tenn. Dec. 30, 2015)6	0
Aquestive Therapeutics, Inc. v. Neurelis, Inc., IPR2019-00450, 2019 WL 3504247 (PTAB Aug. 1, 2019)2	8
Aylus Networks, Inc. v. Apple Inc., 856 F.3d 1353 (Fed. Cir. 2017)6	0
Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, 2017 WL 6405100 (PTAB Dec. 15, 2017)21, 24, 2	8
Boehringer Ingelheim Vetmedica, Inc. v. Schering- Plough Corp., 320 F.3d 1339 (Fed. Cir. 2003)5	3
Broadcom Corp. v. Emulex Corp., 732 F.3d 1325 (Fed. Cir. 2013)	5
Cisco Sys., Inc., v. C-Cation Techs., LLC, IPR2014-00454, 2014 WL 4352301 (PTAB Aug. 29, 2014)	.8
Coalition for Affordable Drugs V LLC v. Hoffman-LaRoche, Inc., IPR2015-01792, 2016 WL 1081666 (PTAB Mar. 11, 2016)6	0
CSL Behring GmBH v. Shire Viropharma Inc., IPR2019-00459, 2019 WL 2866004 (PTAB July 2, 2019)25, 2	28
Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387 (Fed. Cir. 1988)5	55
Fidelity Nat'l Info. Servs., Inc., v. DataTreasury Corp., IPR2014-00489, 2014 WL 4059220 (PTAB Aug. 13, 2014)	.8



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