

UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC
Petitioner

v.

CUBIST PHARMACEUTICALS LLC
Patent Owner

CASE IPR2020-00193

U.S. PATENT NO. 9,138,456 B2

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

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List of Exhibits

- Ex. 1001 United States Patent No. 9,138,456 B2
- Ex. 1002 Prosecution history of United States Patent No. 9,138,456 B2
- Ex. 1003 Declaration of Dr. Raj Suryanarayanan
- Ex. 1004 Cubicin[®] label (downloaded on December 7, 2018 from https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-572_Cubicin_Prntlbl.pdf)
- Ex. 1005 United States Patent No. 6,136,783 (“*Neururkar*”)
- Ex. 1006 United States Patent No. 7,112,565 B2 (“*Sawai*”)
- Ex. 1007 United States Patent Application Publication No. 2010/0137197 A1 (“*Mittal*”)
- Ex. 1008 European Patent Application Publication No. EP 0 386 951 A2 (“*Inman*”)
- Ex. 1009 United States Patent No. 8,835,382 B2
- Ex. 1010 Caspofungin[®] label (downloaded on December 12, 2018 from https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/21227s015lbl.pdf)
- Ex. 1011 Carpenter, J.F., et al., “Rational Design of Stable Lyophilized Protein Formulations: Some Practical Advice,” *Pharmaceutical Research*, vol. 14, no. 8, pp. 969-976 (1997).
- Ex. 1012 Diven, D.G., et al., “Extending Shelf Like Just Makes Sense,” *Mayo Clin. Proc.*, vol. 90, no. 11, pp. 1471-1474 (2015).
- Ex. 1013 European Patent Application Publication No. EP 2 918 324 A1.

- Ex. 1014 *Physicians' Desk Reference*, 60th ed., pp. 1038-1042 (2006).
- Ex. 1015 European Medicines Agency, *Caspofungin Accord: European Public Assessment Report* (2015) (downloaded on July 25, 2019 from https://www.ema.europa.eu/en/documents/assessment-report/caspofungin-accord-epar-public-assessment-report_en.pdf)
- Ex. 1016 European Medicines Agency, *Cubicin: European Public Assessment Report – Scientific Discussion* (2006) (downloaded on July 25, 2019 from https://www.ema.europa.eu/en/documents/scientific-discussion/cubicin-epar-scientific-discussion_en.pdf).

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