

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

Table of Contents

I.	INTRODUCTION.....	1
II.	MANDATORY NOTICES (37 C.F.R. § 42.8).....	1
A.	Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1)).....	1
B.	Related Matters (37 C.F.R. § 42.8(b)(2)).....	1
C.	Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3)).....	2
D.	Service Information (37 C.F.R. § 42.8(b)(4)).....	2
III.	GROUND FOR STANDING (37 C.F.R. § 42.104(a)).....	3
IV.	IDENTIFICATION OF CHALLENGES.....	3
V.	BACKGROUND.....	4
A.	Technology.....	4
B.	The ‘456 Patent.....	7
VI.	PERSON OF ORDINARY SKILL IN THE ART.....	10
VII.	CLAIM CONSTRUCTION.....	11
VIII.	IDENTIFICATION OF HOW EACH CHALLENGED CLAIM OF THE ‘456 PATENT IS UNPATENTABLE.....	12
A.	Challenge #1: Claims 1, 2, and 7-11 are obvious under pre-AIA 35 U.S.C. § 103(a) over the Cubicin® label in view of <i>Neururkar, Mittal, or Sawai</i>	12
1.	Claim 1.....	12
2.	Claim 2.....	27

3.	Claim 7.....	32
4.	Claim 8.....	37
5.	Claim 9.....	39
6.	Claim 10.....	42
7.	Claim 11.....	44
B.	Challenge #3: Claims 1, 2, and 7-11 are obvious under pre-AIA 35 U.S.C. § 103(a) over <i>Inman</i> in view of <i>Neururkar, Sawai, or Mittal</i>	45
1.	Claim 1.....	45
2.	Claim 2.....	49
3.	Claim 7.....	51
4.	Claim 8.....	54
5.	Claim 9.....	55
6.	Claim 10.....	57
7.	Claim 11.....	59
IX.	PETITION SHOULD NOT BE DENIED.....	60
X.	CONCLUSION.....	61

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 Life 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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