

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGILA SPECIALTIES INC.

AND MYLAN PHARMACEUTICALS INC.,

Petitioners,

v.

CUBIST PHARMACEUTICALS, INC.,

Patent Owner.

Case IPR2015-00141

Patent No. 8,058,238

**PATENT OWNER'S PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107**

TABLE OF CONTENTS

I.	Introduction	1
A.	State of the Art Prior to the Invention	2
B.	Description of the Invention	4
II.	Definition of One of Ordinary Skill in the Art.....	6
III.	Claim Construction	8
A.	The Process Limitations Cannot Be Disregarded.....	8
B.	Proposed Terms for Construction.....	11
1.	The claim term “essentially pure” daptomycin should be construed to mean “at least 98% of a sample is daptomycin.”	12
2.	The claim term “substantially pure” daptomycin should be construed to mean “at least 95% of a sample is daptomycin.”	13
3.	Claim terms regarding daptomycin “substantially free,” “essentially free,” or “free of” another compound.....	13
IV.	Ground 1 should be denied because it fails to address each limitation of the challenged claims	15
V.	The Petition should be denied because the asserted grounds are duplicative, redundant, and unclear	17

A. The Petition Alleges No Fewer than 21 Grounds of Invalidity, None of Which Are Identified with Particularity.....17

1. Ground 1 includes two separate grounds.21

2. Ground 4 includes at least three separate grounds.22

3. Ground 5 includes at least seven separate grounds.....24

4. Ground 6 includes at least six separate grounds.30

5. Ground 7 appears to include a single ground, but is unclear.32

B. The Petition Provides No Meaningful Distinction Among the Horizontally and Vertically Redundant Grounds.33

VI. Ground 1 should be denied under 35 U.S.C. § 325(d) because it presents grounds previously presented to the Office35

VII. Conclusion.....40

TABLE OF AUTHORITIES

FEDERAL CASES	PAGE(S)
<i>Amgen Inc. v. F. Hoffman-La Roche Ltd,</i> 580 F.3d 1340 (Fed. Cir. 2009)	8, 11
<i>Cubist Pharms., Inc. v. Hospira, Inc.,</i> C.A. No. 12-376 (GMS), slip op. (D. Del. May 20, 2013).....	12
<i>Cubist Pharms., Inc. v. Hospira, Inc.,</i> Claim Construction Chart (D. Del. Feb. 1, 2013).....	12, 13
<i>Cubist Pharms., Inc. v. Hospira, Inc.,</i> Memorandum Opinion, dated December 8, 2014	12
<i>Greenliant Sys., Inc. v. Xicor LLC,</i> 692 F.3d 1261 (Fed. Cir. 2012)	8
<i>In re Robertson,</i> 169 F.3d 743 (Fed. Cir. 1999)	17
<i>Schumer v. Lab. Computer Sys., Inc.,</i> 308 F.3d 1304 (Fed. Cir. 2002)	20

BOARD DECISIONS*CallCopy, Inc. v. Verint Americas, Inc.,*

IPR2013-00492, Paper 14 (P.T.A.B.).....20

Corning Inc. v. DSM IP Assets B.V.,

IPR2013-00052, Paper 16 (P.T.A.B.).....8, 11

Edmund Optics, Inc. v. Semrock, Inc.,

IPR2014-00583, Paper 9 (P.T.A.B.).....19

Excelsior Med. Corp. v. Lake and Tennant,

IPR2013-00494 Paper 10 (P.T.A.B.).....35

Illumina, Inc. v. Trs. of Columbia Univ.,

IPR2012-00006, Paper 43 (P.T.A.B.).....33

JST Performance, Inc. d/b/a Rigid Industries v. Koninklijke Philips N.V.,

IPR2014-00874, Paper 11 (P.T.A.B.).....17

Liberty Mut. Ins. Co. v. Progressive Cas. Ins. Co.,

CBM2012-00003, Paper 7 (P.T.A.B.).....33

Mitsubishi Plastics, Inc. v. Celgard, LLC,

IPR2014-00524, Paper 27 (P.T.A.B.).....15

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.