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

Patent No. 8,058,238

Case IPR2015 UNASSIGNED

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,058,238

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. INTRODUCTION vi

A. Overview of the '238 Patent 1

B. Brief Overview of the Prosecution History 1

II. GROUNDS FOR STANDING - § 42.104(a) 3

III. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8 3

A. Real Party in Interest 3

B. Related Matters 4

C. Lead and Backup Counsel and Service Information 4

IV. STATEMENT OF THE PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED 5

A. Identification of the Challenge - § 42.104(b) 5

V. LEVEL OF ORDINARY SKILL IN THE ART 5

VI. CLAIM CONSTRUCTION 6

VII. SCOPE AND CONTENT OF THE PRIOR ART 8

A. U.S. Patent No. 4,874,843 ("'843 Patent") [Ex. 1007] 8

B. U.S. Patent No. 4,331,594 ("the '594 Patent") [Ex. 1009] 8

C. U.S. Patent No. 5,912,226 ("the '226 Patent") [Ex. 1010] 9

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

D. Baltz, *Lipopeptide Antibiotics Produced by* Streptomyces roseosporus *and* Streptomyces fradiae, in BIOTECHNOLOGY OF ANTIBIOTICS (W.R. Strohl ed. 1997). ("Baltz") [Ex. 1008] 11

E. Mulligan and Gibbs, *Recovery of Biosurfactants by Ultrafiltration*, **JOURNAL OF CHEMICAL TECHNOLOGY & BIOTECHNOLOGY**, 47:23-9 (1990). ("Mulligan") [Ex. 1013] 12

F. Lin and Jiang, *Recovery and Purification of the Lipopeptide Biosurfactant Bacillus subtilis by Ultrafiltration*, **BIOTECHNOLOGY TECHNIQUES**, 11:413-16 (1997). ("Lin I") [Ex. 1014] 12

G. Lin et al., *General Approach for the Development of High-Performance Liquid Chromatography Methods for Biosurfactant Analysis and Purification*, **JOURNAL OF CHROMATOGRAPHY**, 825:145-49 (1998). ("Lin II") [Ex. 1015] 13

H. U.S. Patent No. 5,227,294 ("'294 Patent") [Ex. 1016] 15

I. Osman et al., *Tuning micelles of a bioactive heptapeptide biosurfactant via extrinsically induced conformational transition of surfactin assembly*, **J. PEPTIDE SCI.**, 4:449-58 (1998). ("Osman") [Ex. 1017] 15

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

J. Tally et al., *Daptomycin: A Novel Agent for Gram-positive Infections*, **EXPERT OPIN. INVEST. DRUGS,** 8:1223-38 (1999). [Ex. 1018] 16

VIII. BACKGROUND FOR UNPATENTABILITY 16

A. Biosurfactant Background 16

B. State of the Art in January 2000 19

IX. EACH GROUND OF UNPATENTABILITY DEMONSTRATES A REASONABLE LIKELIHOOD OF PREVAILING AGAINST THE CHALLENGED CLAIMS OF THE '238 PATENT 21

A. Ground 1: Claims 10-48, 139-143 and 176-192 of the '238 Patent are Anticipated and Obvious Over the '226 Patent 22

B. Ground 2: Claims 21-36, 176, 183, and 186-190 of the '238 Patent are Obvious Over the '843 Patent or the '594 Patent In View of Mulligan, Lin II, the '226 Patent, and the '294 Patent 29

(i) Claims 21-36 29

(ii) Claim 176 is Obvious Over the '843 Patent or the '594 Patent in View of Mulligan, Lin II, the '226 Patent and the '294 35

(iii) Claims 183 and 186-190 are Obvious 36

C. Ground 3: Claims 10-19, 177 and 179 of the '238 Patent are Obvious Over the '843 Patent or the '594 In View of Mulligan, Lin I and/or Lin II and the '226 Patent 39

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

(i) Claims 10-19 are Obvious Over the '843 Patent or the '594 In View of Mulligan, Lin I and/or Lin II and the '226 Patent 39

(ii) Claims 177 and 179 are Obvious Over the '843 Patent or the '594 In View of Mulligan, Lin I and/or Lin II and the '226 Patent 44

D. Ground 4: Claims 20, 43-47, 178, 180, 184-185 and 191-192 of the '238 Patent are Obvious Over the '843 Patent or the '594 in View of Mulligan, Lin II, the '226 Patent and the '294 Patent and Further in View of Osman 46

(i) Claim 20 of the '238 Patent is Obvious Over the '843 Patent or the '594 in View of Mulligan, Lin II, the '226 Patent and the '294 Patent and Further in View of Osman 47

(ii) Claims 43-47 of the '238 Patent are Obvious 49

(iii) Claim 178 of the '238 Patent is Obvious 51

(iv) Claims 180 and 184-185 are Obvious 53

E. Ground 5: Claim 181-182 of the '238 Patent is Obvious Over the '843 Patent In View of Mulligan, Lin II, the '226 Patent and the '594 Patent 56

X. THE OFFICE'S REASONS FOR ALLOWANCE OF THE PATENT WAS INCORRECT AND NOT SUPPORTED BY THE PRIOR ART'S TEACHINGS 58

A. The '226 Patent is Prior Art Under 35 U.S.C. § 102(a) 59

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.