

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

FRESENIUS KABI USA LLC

Petitioner,

v.

CUBIST PHARMACEUTICALS, INC.

Patent Owner.

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Case: IPR2015-01571  
Patent No. 8,058,238

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**FRESENIUS KABI USA LLC'S UPDATED EXHIBIT LIST**

Exhibit No.	Reference
1001	High Purity Lipopeptides, U.S. Patent No. 8,058,238 (filed Apr. 24, 2007) (issued Nov. 15, 2011).
1002	High Purity Lipopeptides, U.S. Patent No. 8,129,342 (filed Sept. 22, 2010) (issued Mar. 6, 2012).
1003	File History U.S. Patent No. 8,058,238
1004	File History U.S. Patent No. 8,129,342
1005	Expert Declaration of Ralph Tarantino, Ph.D. Relating to U.S. Patent No. 8,052,238
1006	Expert Declaration of Ralph Tarantino, Ph.D. Relating to U.S. Patent No. 8,129,342
1007	Chromatographic Purification Process, U.S. Patent No. 4,874,843 (filed Dec. 3, 1987) (issued Oct. 17, 1989).
1008	Richard H. Baltz, <i>Lipopeptide Antibiotics Produced by Streptomyces roseosporus and Streptomyces fradiae</i> , in BIOTECHNOLOGY OF ANTIBIOTICS (W.R. Strohl ed., 1997). (“Baltz”)
1009	Peptide Antibiotics, U.S. Patent No. 4,331,594 (filed Nov. 14, 1980) (issued May 25, 1982).
1010	Anhydro- and Isomer-A-21978C Cyclic Peptides, U.S. Patent No. 5,912,226 (filed Dec. 16, 1991) (issued Jun. 15, 1999).
1011	F.M. Huber et al., <i>The formation of daptomycin by supplying decanoic acid to Streptomyces roseosporus cultures producing the antibiotic complex A21978C</i> , J. BIOTECHNOL. 7:283-92 (1988).
1012	F.M. Huber et al., <i>Dispersal of insoluble fatty acid precursors in stirred reactors as a mechanism to control antibiotic factor distribution</i> , in BIOTECHNOLOGY PROCESSES (Ho and Oldshue eds., 1987).

Exhibit No.	Reference
1013	Catherine N. Mulligan & Bernard F. Gibbs, <i>Recovery of Biosurfactants by Ultrafiltration</i> , J. CHEM. TECHNOL. BIOTECHNOL. 47:23-9 (1990). (“Mulligan”)
1014	Sung-Chyr Lin and Horng-Jyh Jiang, <i>Recovery and Purification of the Lipopeptide Biosurfactant Bacillus subtilis by Ultrafiltration</i> , BIOTECHNOLOGY TECHNIQUES, 11:413-16 (1997). (“Lin I”)
1015	Sung-Chyr Lin et al., <i>General Approach for the Development of High-Performance Liquid Chromatography Methods for Biosurfactant Analysis and Purification</i> , JOURNAL OF CHROMATOGRAPHY, 825:145-49 (1998). (“Lin II”)
1016	Method of Producing Surfactin with the Use of Mutant of <i>Bacillus Subtilis</i> , U.S. Patent No. 5,227,294 (filed June 20, 1991) (issued Jul. 13, 1993).
1017	Mohamad Osman et al., <i>Tuning micelles of a bioactive heptapeptide biosurfactant via extrinsically induced conformational transition of surfactin assembly</i> , J. PEPTIDE SCI., 4:449-58 (1998). (“Osman”)
1018	F.P. Tally et al., <i>Daptomycin: A Novel Agent for Gram-positive Infections</i> , EXPERT OPIN. INVEST. DRUGS 8:1223-38 (1999). (“Tally”)
1019	BIOSURFACTANTS: RESEARCH TRENDS & APPLICATIONS (Catherine N. Mulligan ed., 2014).
1020	Sung-Chyr Lin, <i>Biosurfactant: Recent Advances</i> , J. CHEM. TECH. BIOTECHNOL. 66:109-20 (1996).
1021	Kei Arima et al., <i>Surfactin, a crystalline peptide lipid surfactant produced by Bacillus subtilis: Isolation, characterization and its inhibition of fibrin clot formation</i> , BIOCHEM. BIOPHYS. RES. COMM. 31:488-94 (1968).
1022	Atsushi Kakinuma et al., <i>Confirmation of the structure of surfactin by mass spectrometry</i> , AG. BIOL. CHEM. 33:1669-72 (1969).

Exhibit No.	Reference
1023	A.W. Bernheimer et al., <i>Nature and properties of a cytolytic agent produced by Bacillus subtilis</i> , J. GEN. MICROBIOL. 61:361-69 (1970).
1024	David G. Cooper, <i>Biosurfactants</i> , MICROBIOL. SCI. 3:145-47 (1986).
1025	Dirk Vollenbroich et al., <i>Antimycoplasm properties and application on cell surface of surfactin, a lipopeptide antibiotic from Bacillus subtilis</i> , APPL. ENVIRON. MICROBIOL. 63:44-69 (1997).
1026	Catherine N. Mulligan et al., <i>Selection of microbes producing biosurfactants in media without hydrocarbons</i> , J. FERMENT. TECHNOL. 62:311-14 (1984).
1027	Catherine N. Mulligan & Bernard F. Gibbs, <i>Correlation of nitrogen metabolism with biosurfactant production</i> , APPL. ENVIRON. MICROBIOL. 55:3016-69 (1989).
1028	Catherine N. Mulligan et al., <i>Enhanced biosurfactant production by a mutant Bacillus subtilis strain</i> , APPL. MICROBIOL. 31:486-69 (1989).
1029	Enhanced Production of Biosurfactant Through the Use of a Mutated B Subtilis Strain, U.S. Patent No. 5,037,758 (filed Jan. 1989) (issued Aug. 6, 1991).
1030	H.E. Reiling et al., <i>Pilot plant production of rhamnolipid biosurfactant by Pseudomonas aeruginosa</i> , APPL. ENVIRON. MICROBIOL., 51:985-89 (1986).
1031	Sung-Chyr Lin et al., <i>Structural and immunological characterization of a biosurfactant produced by Bacillus licheniformis JF-2</i> , APPL. ENV. MICROBIOL. 60:31-8 (1994).
1032	Jitendra D. Desai and Ibrahim M. Banat, <i>Microbial production of surfactants and their commercial potential</i> , MOL. BIOL. REV. 61:47-64, 57 (1997).

Exhibit No.	Reference
1033	Lakey and Ptak, <i>Fluorescence Indicates a Calcium-Dependent Interaction Between the Lipopeptide Antibiotic LY146032 and Phospholipid Membranes</i> , BIOCHEM. 27:4639-4645 (1988).
1034	Anhydro-And Isomer-A-21978C Cyclic Peptides, U.S. Reissued Patent No. 39, 071 (filed Apr. 11, 2000) (reissued Apr. 18, 2006).
1035	21 C.F.R. §600(3)(r) (1998)
1036	21 C.F.R. § 610.13 (1998).
1037	Sweadner, K. et al., <i>Filtration Removal of Endotoxin (Pyrogens) in Solution in Different States of Aggregation</i> , APPLIED AND ENVIRONMENTAL MICROBIOLOGY, 34:382-385 (1997) (“Sweadner”)
1038	Kunz, C. et al., <i>Human-milk proteins: analysis of casein and casein subunits by anon-exchange chromatography, gel electrophoresis, and specific staining methods</i> , Am. J. Clin. Nutr. 1990; 51:37-46 (1990).
1039	Declaration of Daniel P. Margolis in Support of Motion for <i>Pro Hac Vice</i> Admission Under 37 C.F.R. § 42.10(c)
1040	Declaration of Robert V. Cerwinski in Support of Motion for <i>Pro Hac Vice</i> Admission Under 37 C.F.R. § 42.10(c)

Respectfully submitted,

Dated: August 13, 2015

/Elizabeth J. Holland/

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