IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 12-367-GMS
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION

I. INTRODUCTION

In this patent infringement action, plaintiff Cubist Pharmaceuticals, Inc. ("Cubist") alleges that pharmaceutical products proposed by defendant Hospira, Inc. ("Hospira") infringe the asserted claims of the patents-in-suit. (D.I. 1.) The court held a five-day bench trial in this matter on February 18 through February 24, 2014. (D.I. 121–125.) Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning the validity of the patents-in-suit and whether Hospira's proposed products infringe the patents-in-suit. (D.I. 126–28.)

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that: (1) the Certificate of Correction issued for the RE'071 Patent is not invalid, and therefore Hospira's products infringe the RE'071 Patent; (2) the RE'071 Patent is not invalid for lack of written description; (3) the RE'071 Patent is not invalid for improper recapture; (4) a revision to the court's claim construction of the term "daptomycin" in the '967, '689, '238, and '342 Patents is not warranted, and therefore Hospira's products infringe the '967, '689, '238, and '342 Patents; (5) the '967, '689, '238, and '342 Patents are not invalid for lack of written description; (6) the asserted claims of the '967 Patent are invalid

due to anticipation; (7) the asserted claims of the '967 and '689 Patents are invalid due to obviousness; (8) claim 98 of the '238 Patent is invalid due to anticipation; (9) the asserted claims of the '238 and '342 Patents are invalid due to obviousness; (10) Hospira's § 102(f) derivation defense is untimely and precluded; and (11) each of the parties' Rule 52(c) motions are granted in part and denied in part. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT[1]

A. The Parties

1. Plaintiff Cubist Pharmaceuticals Inc. ("Cubist") is a Delaware corporation having a principal place of business at 65 Hayden Avenue, Lexington, Massachusetts.

2. Hospira, Inc. ("Hospira") is a Delaware corporation having a principal place of business at 275 North Field Drive, Lake Forest, Illinois.

3. The court has subject matter jurisdiction, as well as personal jurisdiction over all parties.

B. Background

4. Cubicin® (daptomycin for injection) is an intravenous bactericidal antibiotic approved by the Food and Drug Administration ("FDA") for the treatment of infections caused by certain Gram-positive bacteria, such as *Staphylococcus aureus*, including methicillin-resistant strains, also known as MRSA.

5. Cubicin® was approved for the treatment of complicated skin and skin structure infections in 2003. It was approved for the treatment of bloodstream infections (bacteremia), including right-sided infective endocarditis caused by MRSA, as well as by methicillin-susceptible *Staphylococcus aureus*, in 2006.

6. The '967 Patent, the '689 Patent, the RE'071 Patent, the '238 Patent, and the '342 Patent (described below) have been listed in connection with Cubicin® in the FDA's publication,

[1] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 109, Ex. 1.) The court takes most of its findings of fact from the parties' uncontested facts. Where necessary, the court has overruled objections to the inclusion of these facts. The court has also reordered and renumbered some paragraphs, corrected some spelling and formatting errors, and made minor edits for the purpose of concision and clarity that it does not believe alters the meaning of the paragraphs from the Pretrial Order. Otherwise, any differences between this section and the parties' statement of uncontested facts are unintentional.

The court's findings of fact with respect to matters that were the subject of dispute between the parties are included in the Discussion and Conclusions of Law section of this opinion, preceded by the phrase "the court finds" or "the court concludes."

Approved Drug Products with Therapeutic Equivalence Evaluations, which is commonly referred to as the "Orange Book."

C. The Patents-in-Suit

7. U.S. Patent Number 6,468,967 ("the '967 Patent")—"Methods for Administration of Antibiotics"—issued on October 22, 2002. The '967 Patent is assigned to Cubist.

8. The '967 purports to claim priority to Provisional Application Number 60/101,828, filed on September 25, 1998, and to Provisional Application Number 60/125,750, filed on March 24, 1999.

9. The '967 Patent lists Frederick B. Oleson, Jr. and Francis P. Tally as inventors.

10. U.S. Patent Number 6,852,689 ("the '689 Patent")—"Methods for Administration of Antibiotics"—issued on February 8, 2005. The '689 Patent is assigned to Cubist.

11. The '689 Patent is a continuation of U.S. Application Number 09/406,568, now the '967 Patent, and purports to claim priority to Provisional Application Number 60/101,828, filed on September 25, 1998, and to Provisional Application No. 60/125,750, filed on March 24, 1999. The '689 Patent is subject to a terminal disclaimer.

12. The '689 Patent lists Frederick B. Oleson, Jr. and Francis P. Tally as inventors.

13. U.S. Patent Number 8,058,238 ("the '238 Patent")—"High Purity Lipopeptides"—issued on November 15, 2011. The '238 Patent is assigned to Cubist.

14. The '238 Patent claims priority to U.S. Application Number 10/747,485, filed on December 29, 2003, which is a division of U.S. Application Number 09/735,191, filed on November 28, 2000, now U.S. Patent Number 6,696,412, and Provisional Application Number 60/177,170, filed on January 20, 2000.

15. The '238 Patent lists Thomas Kelleher, Jan-Ji Lai, Joseph P. DeCourcey, Paul Lynch, Maurizio Zenoni, and Auro Tagliani as inventors.

16. U.S. Patent Number 8,129,342 ("the '342 Patent")—"High Purity Lipopeptides"—issued on March 6, 2012. The '342 Patent is assigned to Cubist.

17. The '342 Patent claims priority to U.S. Application Number 11/739,180, filed on April 24, 2007, now the '238 Patent, which is a continuation of U.S. Application Number 10/747,485, filed on December 29, 2003, which is a division of U.S. Application Number 09/735,191, filed on November 28, 2000, now U.S. Patent Number 6,696,412, and Provisional Application Number 60/177,170, filed on January 20, 2000. The '342 Patent is subject to a terminal disclaimer to the '238 Patent.

18. The '342 Patent lists Thomas Kelleher, Jan-Ji Lai, Joseph P. DeCourcey, Paul Lynch, Maurizio Zenoni, and Auro Tagliani as inventors.

19. U.S. Patent Number RE39,071 ("the RE'071 Patent")—"Anhydro- and Isomer-A-21978C Cyclic Peptides"—issued on April 18, 2006. The RE'071 Patent is assigned to Cubist.

20. The RE'071 Patent is a reissue of U.S. Patent Number 5,912,226 ("the '226 Patent").

21. The RE'071 Patent is a continuation of U.S. Application Number 07/670,375, filed on March 14, 1991, which is a continuation of U.S. Application Number 07/060,148, filed June 10, 1987.

22. The RE'071 Patent lists Patrick J. Baker, Manuel Debono, Khadiga Z. Farid and R. Michael Molloy as inventors

23. A Request for Certificate of Correction for the RE'071 Patent was filed on October 18, 2007, and a Certificate of Correction issued for the RE'071 Patent on January 29, 2008.

1. The Asserted Claims[2]

24. Cubist is asserting claims 16, 17, 34, and 35 of the '967 Patent.

25. Cubist is asserting claims 51 and 52 of the '689 Patent.

26. Cubist is asserting claims 91, 98, and 187 of the '238 Patent.

27. Cubist is asserting claims 23 and 53 of the '342 Patent.

28. Cubist is asserting claims 18 and 26 of the RE'071 Patent.

a. '967 Patent, Claim 16

29. Claim 16 of the '967 Patent reads:

> The method according to claim 14, [comprising the step of administering to a human patient in need thereof a therapeutically effective amount of daptomycin . . . at a dosage interval that minimizes skeletal muscle toxicity], wherein the dose is 4 mg/kg [repeatedly] administered once every 24 hours.

[2] Several of the asserted claims are dependent claims. For clarity, the court has included language from the unasserted claims on which they depend to offer a more complete view of what the claims cover.

b. '967 Patent, Claim 17

30. Claim 17 of the '967 Patent reads:

> The method according to claim 14, [comprising the step of administering to a human patient in need thereof a therapeutically effective amount of daptomycin . . . at a dosage interval that minimizes skeletal muscle toxicity], wherein the dose is 6 mg/kg [repeatedly] administered once every 24 hours.

c. '967 Patent, Claim 34

31. Claim 34 of the '967 Patent reads:

> The method according to claim 33 [for treating or eradicating a bacterial infection in a human patient in need thereof, comprising the step of administering a therapeutically effective amount of daptomycin . . . to the patient at a dosage interval that minimizes skeletal muscle toxicity, wherein the daptomycin dose is repeatedly administered at the dosage interval of once every 24 hours . . . until said bacterial infection is treated or eradicated], wherein the dose is 4 mg/kg.

d. '967 Patent, Claim 35

32. Claim 35 of the '967 Patent reads:

> The method according to claim 33 [for treating or eradicating a bacterial infection in a human patient in need thereof, comprising the step of administering a therapeutically effective amount of daptomycin . . . to the patient at a dosage interval that minimizes skeletal muscle toxicity, wherein the daptomycin dose is repeatedly administered at the dosage interval of once every 24 hours . . . until said bacterial infection is treated or eradicated], wherein the dose is 6 mg/kg.

e. '689 Patent, Claim 51

33. Claim 51 of the '689 Patent reads:

> The method according to claim 48 [for administering daptomycin, comprising the step of administering to a human patient in need thereof a therapeutically effective amount of daptomycin in a dose of at least 3 mg/kg of daptomycin at a dosage interval that minimizes skeletal muscle toxicity, wherein the dose is repeatedly administered

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