IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 12-cv-367 (GMS)
	)	
HOSPIRA, INC.,	)	
	)	
Defendant.	)	
	)	

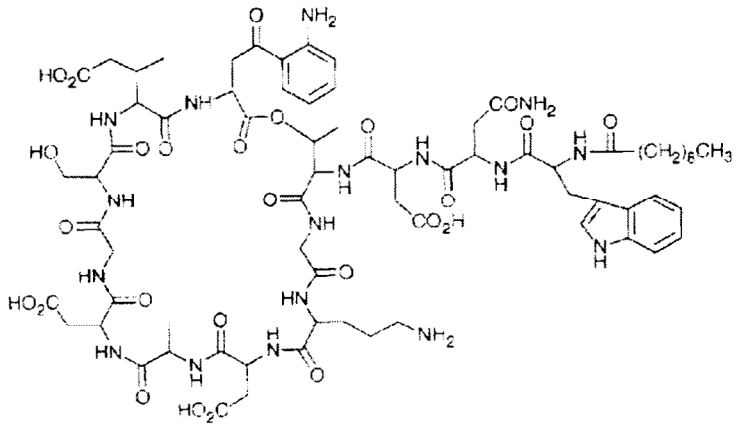
ORDER CONSTRUING THE TERMS OF U.S. PATENT NOs. 6,468,967; 8,852,689; 8,129,342; and RE 39,071

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 6,468,967 ("the '967 Patent"), 8,852,689 ("the '689 Patent"), 8,058,238 ("the '238 Patent"), 8,129,342 ("the '342 Patent"), and RE 39,071 ("RE '071") (collectively, "the patents-in-suit"):

The '967, '689, '238, and '342 Patents

1. The term "daptomycin" is construed to mean "the cyclic lipopeptide antibiotic derived from the fermentation of Streptomyces roseosporus, comprised of a decanoyl side chain linked to the N-terminal tryptophan of a cyclic 13-amino acid peptide, i.e.,

CUBIST 2106



(LY 146032) or a pharmaceutically acceptable salt thereof."[1]

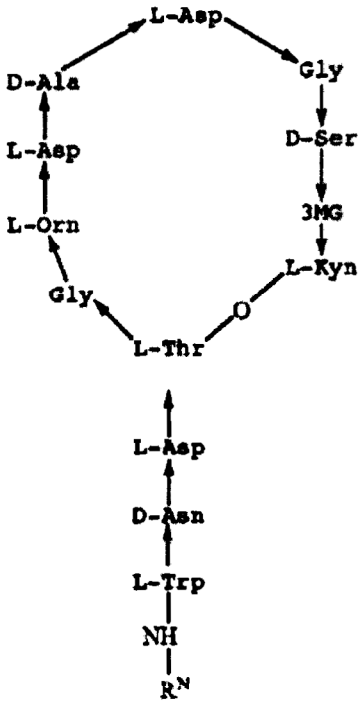
[1] The court rejects the defendant's proposed construction of this term, which the parties agrees should be construed the same for each of the patents-in-suit. The defendant's proposed construction, "the compound described in the Baltz article at Fig. 1a (Biotechnology of Antibiotics, 2nd Ed., ed. By Strohl, 415-435 (1997) and in the Tally article at Fig. 1 (Exp. Opin. Invest. Drugs, 8:1223-1238 (1999)), (i.e., having the L-Asn configuration)," seeks to define daptomycin by the stereochemistry of the thirteen amino acids that comprise the compound. (D.I. 39 at 6; D.I. 37 at 15-17.) Specifically, the defendant asserts that the stereochemistry of these amino acids should be construed as described in the prior art referenced in the patents and as depicted in a diagram illustrating the L-Asn and D-Asn structure of the claimed molecule. (D.I. 27 at 15-16.) Thus, the defendant contends that these amino acids should be defined by what was known of their stereochemistry at the time of the invention, despite the fact that scientists have since discovered, using new technology, that the stereochemistry of one of the thirteen amino acids was incorrect. The court finds the defendant's proposed construction to be inconsistent with the claim language, the specification, and the intrinsic record for the reasons that follow.

First, and as the plaintiff correctly highlights, neither the claim language nor the patent specification identifies the stereochemistry of daptomycin's amino acids. Rather, the specification refers to daptomycin as the natural product obtained from fermentation of Streptomyces roseosporus, which is the fermentation of bacteria. *See* '967 Patent at col. 1:42-47; '238 Patent at col. 1:60-63; D.I. 39 at 5-6. Thus, while the defendant seeks to define daptomycin based exclusively on a diagram depicting stereochemical orientation, including the incorrect stereochemistry for one of the amino acids, the plaintiff's proposed construction identifies daptomycin as a fermentation product with antibiotic activity and shows the thirteen amino acids that comprise daptomycin as they are presented in the high purity patents, without the specific stereochemical orientation of each. (D.I. 39 at 6.) The court finds this latter construction appropriate because it is consistent with the intrinsic record. As noted, at the time daptomycin was first discovered in the 1980s, scientists thought, based on scientific methods available at the time, that the asparagine amino acid was oriented in the "L" configuration. (*Id.* at 7.) Subsequently, in the early 2000s, scientists using modern techniques were able to discover that daptomycin's asparagine is, in fact, oriented in the "D" configuration. The defendants' attempt to construe daptomycin as defined by its stereochemistry—and the wrong stereochemistry for the asparagine amino acid—when the claim language and specification does not do so, is inappropriate. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14 (Fed. Cir. 2005) ("[T]he specification 'is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.'" (citation omitted)).

Second, the claims, specifications, and file histories of the relevant dosing patents make clear that daptomycin is a fermentation product with antibiotic properties. Specifically, all of the asserted claims of the dosing patents use the term daptomycin to refer to a clinical product that is "therapeutically effective" and is to be "administer[ed] to a human patient." *See, e.g.*, '967 Patent at col. 14:50-56, Claim 1. The dosing patents' claims do not recite the chemical structure of daptomycin or its stereochemistry, such that a person of ordinary skill in the art reading the claims would understand that daptomycin refers to the highly potent antibacterial Streptomyces roseosporus fermentation product, because that fermentation product was the therapeutically active antibiotic developed for clinical use. Instead, the patent specifications consistently state that daptomycin: is a fermentation product antibiotic; has a highly potent antibiotic that has been demonstrated to have clinical efficacy in pre-clinical and clinical studies conducted prior to

The RE '071 Patent

2. The term "Formula 3 compound" is construed to mean "an A21978C cyclic peptide of Formula 3



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the discovery of the claimed dosing methods; and, as shown through the examples and embodiments, is therapeutically effective, such that "[d]aptomycin may be administered . . . until the bacterial infection is eradicated or reduced." *See, e.g.*, '967 Patent at col. 1:42-47; *id.* at col. 1:63-67; *id.* at col. 2:31-33; *id.* at col. 6:19-30. Therefore, the court finds that the defendant's proposed construction is incorrect because this construction, which includes the flawed stereochemistry for the asparagine amino acid, is not a compound that has ever been shown to result from Streptomyces roseosporus fermentation and does not have antibiotic properties.

Finally, the court concludes that the defendant's proposed construction would, by focusing exclusively on stereochemistry, inappropriately exclude the preferred embodiments of the dosing patents. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (noting that a construction that excludes the preferred embodiment "is rarely, if ever, correct."). The sole support for the defendant's proposed construction appears in figures that are not presented in the dosing patents and, instead, come from two articles cited in the patents' specifications: Baltz, BIOTECHNOLOGY OF ANTIBIOTICS, 415-35 (Strohl, 2nd ed. 1997) and Francis P. Tally *et al.*, *Daptomycin: A Novel Agent for Gram-Positive Infections*, 8 EXP. OPIN. INVST. DRUGS, 1223-1238 (1999). To this end, a person of ordinary skill in the art reading the dosing patents would not understand the claim term daptomycin to be limited by the figures in those articles depicting stereochemistry, particularly when doing so would exclude the detailed discussions of daptomycin's properties in the specifications themselves. *See id.*; *see also Phillips*, 415 F.3d at 1313-14. Indeed, even the Baltz and Tally articles, read as a whole, describe daptomycin as a "highly active" "potent antibiotic" produced by fermentation of Streptomyces roseosporus and summarizes testing where daptomycin was administered to various patients. (D.I. 39 at 10-11.)

Thus, in view of the foregoing, the court concludes that the defendant's proposed construction is inconsistent with the claim language, the specification, and the intrinsic evidence and adopts the plaintiff's proposed construction of the term.

wherein R^N is n-decanoyl (i.e., LY 146032).[2]

Dated: May 20, 2013

CHIEF, UNITED STATES DISTRICT JUDGE

[2] The court rejects the defendants' proposed construction. The parties do not dispute that, on October 18, 2007, the plaintiff filed a request with the Patent and Trademark Office ("the PTO") to correct the stereochemistry of daptomycin in the claims and specification of the RE '071 Patent. (D.I. 48 at 2.) This request attached a paper by Vivian Miao et al., *Daptomycin Biosynthesis in Streptomyces roseosporus*, 151 MICROBIOLOGY 1507 (2005), which explained the error in daptomycin's stereochemistry and how the error had been discovered. (*Id.* (citing RE '071 File History, 10/18/2007 Request for Certificate of Correction (J.A. at 362-64)).) The PTO issued a Certificate of Correction that changed all instances of L-Asn in the RE '071 Patent to D-Asn. (*Id.* (citing RE '071 File History, 1/29/2008 Certificate of Correction (J.A. at 365)).) Despite this correction, the defendant argues that this claim term should be construed to include the pre-Certificate of Correction incorrect stereochemistry because: (1) "even after the correction, a skilled artisan faced with conflicting evidence would still have concluded that the claimed compound was L-Asn daptomycin, not D-Asn datomycin" because "looking at the entire specification, and through the lens of the relevant prior art," that skilled artisan would find "no teaching in the patent specification or other intrinsic evidence that a D-Asn antibiotic drug was what the inventors thought they had discovered" (D.I. 37 at 11); and (2) the plaintiff's Certificate of Correction is "ineffective and, thus, the Court should be construing the original claims, not the corrected claims" as the "allegedly corrected mistake is not a clerical or typographical error" and, therefore, is not effective (*id.* at 11-12). The court disagrees.

First, and with regard to the defendant's contention that a skilled artisan "would simply not believe" the corrected claims of the RE '071 Patent, the court does not find support for this argument. Specifically, the plaintiff submitted the Miao paper to the PTO in conjunction with its request for a Certificate of Correction, which discloses the correct structure and the scientific studies and experimental evidence to support the revised structure. (D.I. 48 at 4 (citing RE '071 File History, 10/18/2007 Request for Certificate of Correction at 1-2 (J.A. at 362-63)).) The defendant has not presented support for its assertion that a person of ordinary skill in the art would disbelieve the teachings in Miao in favor of earlier references depicting the erroneous stereochemistry. Second, the court agrees with the plaintiff that the defendant's contention that the Certificate of Correction is ineffective, is a matter to be resolved on summary judgment or at trial, rather than at the claim construction stage. *See Eon Corp. IP Holdings, LLC v. T-Mobile USA, Inc.*, No. 10-cv-0379, 2012 WL 405492, at *19 (E.D. Tex. Feb. 8, 2012) ("[W]hether the CoC is valid . . . is not a claim construction issue, but rather an issue for summary judgment"). While the defendant argues that it "is not presently seeking summary judgment of . . . invalidity of any of the asserted patents," it does request that the court determine whether the Certificate of Correct is indeed valid. A challenge to the validity of a certificate of correction is often a challenge to the validity of the patent's claims. *See Superior Fireplace Co. v. Majestic Products. Co.*, 270 F.3d 1358, 1366-67 (Fed. Cir. 2001) ("Because [the] certificate of correction became part of the '534 patent and changed claim language, [the alleged infringer's] challenge to the certificate amounted to a challenge to the corrected claim itself."). Here, the court agrees with the plaintiff that the determination of whether the stereochemistry correction is properly considered a correction of "minor character" presents questions requiring expert testimony regarding the nature of the error and its correction. *See AT&T Corp. v. Microsoft Corp.*, No. 01-cv-4872, 2004 WL 292321, at *8 (S.D.N.Y. Feb. 17, 2004) (citing *Tillotson, Ltd. v. Walbro Corp.*, 831 F.2d 1033, 1039 (Fed. Cir. 1987)). In fact, both parties' arguments regarding the Certificate of Correction rely on facts the court will need to determine. *See, e.g., Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Solutions PC*, 482 F.3d 1347, 1354 (Fed. Cir. 2007) ("[W]hether the error and its correction would both be clearly evident to one of skill in the art[] has been treated as a factual question."). In consideration of the record before it, the court concludes that the defendants have failed to present clear and convincing evidence that the Certificate of Correction is invalid. *See Superior Fireplace*, 270 F.3d at 1367. The defendant also has not presented evidence that the correction was not of minor characteristic. Consequently, the court concludes that the plaintiff's proposed construction, which reflects the stereochemistry change allowed by the Certificate of Correction, is appropriate.

The court recognizes that the parties did not include a paragraph in their Scheduling Order providing the opportunity to file letters requesting permission to file a motion for summary judgment. As a result, the court will issue an Amended Scheduling Order providing the parties with this opportunity and a deadline for such submissions.