IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACIA & UPJOHN COMPANY, Plaintiff, v. SICOR INC. AND SICOR PHARMACEUTICALS, INC., Defendants.	)	Civil Action No. 04-833 (KAJ) ~~FILED UNDER SEAL~~ UNSEALED 8/25/06

MEMORANDUM OPINION

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Wilmington, Delaware

JORDAN, District Judge

I. INTRODUCTION

This is a patent infringement case. Pharmacia & Upjohn Company, LLC ("Pharmacia") has sued Sicor Inc. and Sicor Pharmaceuticals, Inc. (collectively, "Sicor"), alleging infringement of U.S. Patent No. 6,107,285 (issued Aug. 22, 2000) (the "'285 patent"). Before me are the parties' requests for construction of the disputed claim language in the patent, as well as four summary judgment motions. Sicor has filed a Motion for Summary Judgment on Non-Infringement, or in the Alternative, Invalidity for Lack of Written Description (Docket Item ["D.I."] 246), and a Motion for Summary Judgment on Anticipation (D.I. 254). Pharmacia has filed a Motion for Summary Judgment on Sicor's Unclean Hands Affirmative Defense (D.I. 248) and a Motion for Summary Judgment on Sicor's Anticipation Affirmative Defense (D.I. 252). Jurisdiction is appropriate under 28 U.S.C. §§ 1331 and 1338.

For the reasons that follow, including my decision on claim construction, I will deny Sicor's Motion for Summary Judgment of Non-Infringement, and deny its alternative Motion for Summary Judgment of Invalidity for Lack of Written Description. Additionally, I will grant Pharmacia's Motion for Summary Judgment on Sicor's Anticipation Defense, and deny Sicor's Motion for Summary Judgment on Anticipation. Finally, I will deny Pharmacia's Motion for Summary Judgment on Sicor's Unclean Hands Affirmative Defense.

II. BACKGROUND

A. *Procedural Background*

Pharmacia filed its First Amended Complaint against Sicor on November 9, 2004, alleging that Sicor is willfully infringing the '285 patent. (D.I. 27.) More specifically, Pharmacia asserts that Sicor is infringing claims 9 and 13 of the patent.[1] (D.I. 232 at 1.) In its Second Amended Answer, Sicor denied willfully infringing the patent and asserted counterclaims that the '285 patent is invalid and that it is unenforceable because of Pharmacia's inequitable conduct. (D.I. 219 at 4-19.) Sicor also asserted the affirmative defenses of unclean hands, equitable estoppel, and laches. (D.I. 219 at 3-4.) The parties are scheduled to try this case to a jury beginning on November 20, 2006.

The '285 patent issued from U.S. Patent Application No. 07/827,742 (the "'742 application"), which was a divisional application of U.S. Patent Application No. 07/503,856 (the "'856 application"). Both of these applications, as well as other related U.S. Patent Applications, claimed priority from U.K. Patent Application 8519452 (filed Aug. 2, 1985).

B. *The Disclosed Technology*

The '285 patent discloses a "sterile, pyrogen-free, ready-to-use solution of an anthracycline glycoside ... [which] is particularly advantageous for the administration by injection of the anthracycline glycoside drugs ... in the treatment of both human and

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[1] Claim 9 depends from independent claim 1, and claim 13 depends from claim 12, which depends from claim 11, which depends from independent claim 1.

animal tumors." ('285 patent Abstract.) Independent claim 1 of the '285 patent, from which both of the asserted claims ultimately depend, claims:

> A physiologically acceptable solution of anthracycline glycoside selected from the group consisting of idarubicin hydrochloride, doxorubicin hydrochloride and epirubicin hydrochloride dissolved in a physiologically acceptable aqueous solvent, having a pH adjusted to from 2.5 to 5.0 with a physiologically acceptable acid selected from the group consisting of hydrochloric acid, sulfuric acid, phosphoric acid, methane sulfonic acid, and tartaric acid, the concentration of said anthracycline glycoside being from 0.1 to 100 mg/ml, wherein said solution is contained in a sealed container.

('285 patent at 23:5-15.) Claim 9 claims:

> The anthracycline glycoside solution of claim 1, wherein said solution exhibits storage stability as a result of said pH being adjusted to the said pH range using said acids.

(*Id.* at 24:12-14.) Finally, claim 13, re-written to incorporate the limitations of claims 11 and 12 from which claim 13 depends, claims:

> The solution of claim 1 wherein the concentration of anthracycline glycoside is about 1 mg/ml, the physiologically acceptable acid is hydrochloric acid, and the anthracycline glycoside is idarubicin hydrochloride.

(*Id.* at 24:18-23.)

III. APPLICABLE LAW/STANDARD OF REVIEW

A. *Patent Infringement*

A patent infringement analysis involves two steps: claim construction and then the application of the construed claim to the accused process or product. *Markman*, 52 F.3d at 976. The first step, claim construction, has been held to be purely a matter of law. *Cybor*, 138 F.3d at 1454-56. The second step, application of the claim to the accused product, is a fact-specific inquiry. *See Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001) (Patent infringement, "whether

literal or under the doctrine of equivalents, is a question of fact."). The patent owner has the burden of proving infringement by a preponderance of the evidence. *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 758 (Fed. Cir. 1984) (citing *Hughes Aircraft Co. v. United States,* 717 F.2d 1351, 1361 (Fed. Cir. 1983)). Summary judgment is appropriate in patent infringement suits when it is apparent that only one conclusion regarding infringement could be reached by a reasonable jury. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1323 (Fed. Cir. 2001).

B. *Claim Construction*

Patent claims are construed as a matter of law. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454-56 (Fed. Cir. 1998) (en banc). "[T]he words of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). That ordinary meaning "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313.

To determine the ordinary meaning of a term, the court should review "the same resources as would" the person of ordinary skill in the art. *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998). Those resources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

"[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms." *Phillips*, 415 F.3d at 1314. Both "the context in which a term is used in the asserted claim" and the "[o]ther claims of the patent in question" are useful for understanding the ordinary meaning. *Id.*

"[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.'" *Id.* at 1315 (quoting *Vitronics*, 90 F.3d at 1582). In short, the claims "must be read in view of the specification, of which they are a part." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Thus, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

On occasion, "the specification may reveal a special definition given to a claim term . . . that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). The specification may also "reveal an intentional disclaimer, or disavowal, of claim scope by the inventor . . . [, which] is regarded as dispositive." *Id.* (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001)).

The court "should also consider the patent's prosecution history." *Markman*, 52 F.3d at 980. "Like the specification, the prosecution history provides evidence of how the [Patent and Trademark Office] and the inventor understood the patent." *Phillips*,

415 F.3d at 1317 (citing *Lemelson v. Gen. Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992)).

The court may rely on extrinsic evidence, which is "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. In particular, "dictionaries, and especially technical dictionaries, . . . have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology." *Phillips*, 415 F.3d at 1318 (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)). However, extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n*, 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

During claim construction, "[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." *Phillips*, 415 F.3d at 1324.

C. *Summary Judgment*

Pursuant to Federal Rule of Civil Procedure 56(c), a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to

judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a genuine issue of material fact, a court must review the evidence and construe all inferences in the light most favorable to the non-moving party. *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (internal citation omitted). The non-moving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(c). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal citation omitted). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

IV. DISCUSSION

A. *Claim Construction*

The disputed terms "physiologically acceptable," "anthracycline glycoside," and "sealed container" each appear in claim 1 of the '285 patent. The term "storage stability" appears only in claim 9 of the patent.

1. "physiologically acceptable"

a. The Parties' Proposed Constructions

Pharmacia asserts that "physiologically acceptable" means that "the substance is stable, sterile, pyrogen-free, and otherwise suitable for administration to humans or animals." (D.I. 232 at 16.) Pharmacia cites to the ordinary meaning of the term, as well as to the language of claims 1 and 8 of the '285 patent, the specification, and the prosecution history. (*Id.* at 16-23.) Sicor argues that "physiologically acceptable" should be construed to mean only that the solution is "suitable for administration to humans or animals." (D.I. 234 at 8.) Sicor cites to the language of claims 1 and 8, and to the doctrine of claim differentiation, in support of its proposed construction. (*Id.* at 8-10.) Sicor also cites to the specification and the prosecution history of the patent in further support of its arguments. (*Id.* at 10-12.)

b. The Court's Construction

The language of the patent makes clear that the invention of the patent is directed toward an injectable solution. (*See, e.g.*, '285 patent at 1: 7-8 ("stable intravenously injectable ready-to-use solution"); *id.* at 1:53-54 ("stable, therapeutically acceptable intravenously injectable solution"); *id.* at 4:42, 44-45 ("administering . . . an injectable solution"; "injectable solutions are administered b[y] rapid intravenous injection").) In fact, the title of the patent is "Injectable Ready-to-Use Solutions Containing an Anti-Tumor Anthracycline Glycoside." (*Id.* at 1.) Based on all of these references to an injectable solution, it appears from the language of the patent that the only way that anthracycline glycoside can be administered to a human or an animal is

through an injection. (*See also* Markman Hearing Transcript, D.I. 277 at 48:21-49:10.) The patent also describes the solution as being sterile and pyrogen-free. (*See* '285 patent at 1:58 (sterile, pyrogen-free, anthracycline glycoside solution").)

Sicor's lawyer admitted during the Markman hearing that "when you are talking about something that is intravenously injectable, sterility, pyrogenicity, those things are important." (Markman Hearing Transcript, D.I. 277 at 46:23-25.) He also stated "for an injectable solution to be dispensable to humans, it has to be sterile and pyrogen-free." (*Id.* at 53:19-21.) Thus, even under Sicor's own definition of "physiologically acceptable," which Sicor claims means only that the solution is "suitable for administration to humans or animals," (D.I. 234 at 8), the solution of the patent must be sterile and pyrogen-free. As a result, based on the language of the patent, which repeatedly describes the claimed solution as being "injectable," and based on the admissions of Sicor's lawyer, it is clear that "physiologically acceptable" must be construed to mean that the solution is sterile and pyrogen-free for it to be suitable for administration to humans and animals.[2]

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[2] The best argument that can be made that sterility is not part of the term "physiologically acceptable" is that, in the written description of the invention, the patent describes a process for making the claimed solution, "which process comprises dissolving a physiologically acceptable salt ... in a physiologically acceptable solvent therefor; optionally adding a physiologically acceptable acid ... and passing the resulting solution through a sterilising filter." ('285 patent at 3:64-70.) Thus, the patent describes sterilizing the solution made of "physiologically acceptable" reagents. However, this piece of the written description alone, describing the process for making the invention, does not change the fact that for the solution to be capable of administration to humans and animals, it must be sterile and pyrogen free. Additionally, even though the "physiologically acceptable" solvent, salt, and acid are sterile prior to use, they may have to be re-sterilized before administration to a patient.

Sicor makes much of the fact that the '285 patent uses the term "physiologically acceptable" in claim 1, and "a stable, intravenously injectable, sterile, pyrogen-free doxorubicin solution" in claim 8. (D.I. 234 at 8-10.) Sicor argues that Pharmacia's use of the language "stable, intravenously injectable, sterile, pyrogen-free" in claim 8 shows that Pharmacia "knew how to and in fact used that specific language" when it intended to. (*Id.* at 9.) This argument, however, does not overcome the repeated references in the patent to an injectable solution, and Sicor's admission that for an injectable solution to be suitable for administration to humans and animals, it must be sterile and pyrogen-free. Therefore, I will construe the term "physiologically acceptable" to mean "the substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals."[3]

2. "anthracycline glycoside"

a. The Parties' Proposed Constructions

The parties dispute whether "anthracycline glycoside," as it is used in the patent, is limited only to a non-lyophilized preparation[4] of that compound, as Sicor contends, or

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[3] Although Pharmacia's proposed construction also requires that a physiologically acceptable solution be "stable," I do not include that limitation in my construction here. Unlike the limitations of "sterile" and "pyrogen-free," the specification and prosecution history of the patent do not repeatedly discuss the importance of "stability" to the invention. (*See supra* at section IV.1.b.; *see also* D.I. 232, Ex. 4 at PI 775 (describing solution as "sterile, pyrogen-free"); *id.*, Ex. 6 at PI 878-79 ("The solution must also be sterile and pyrogen free.") (emphasis in original).)

[4] Sicor uses the term "non-lyophilized preparate" in its construction. The patent appears to use the terms "preparate" and "preparation" interchangably. (See '285 patent at 1:45-51.) "Preparate," although not a word used in common parlance, is the past participle of the verb "to prepare." *See Webster's Third New International Dictionary* 1790 (Unabridged) (1986).

whether it is not so limited, as Pharmacia contends. The parties agree, however, on the chemical structure of anthracycline glycoside.[5] Pharmacia contends that "anthracycline glycoside" should be construed to mean a class of chemical compounds having the generic structure set forth in note 5, *supra*. (D.I. 232 at 25.) Pharmacia relies on the fact that the structure of "anthracycline glycoside" was known in the art at the time of the invention, and argues that the definition of the term should end there. (*Id.*)

Sicor, on the other hand, argues that "anthracycline glycoside" should be construed to mean a non-lyophilized preparation of the class of chemical compounds having the generic structure set forth in note 5, *supra*. (D.I. 231 at 2.) Sicor asserts that the written description of the invention disclaims coverage of a non-lyophilized form of anthracycline glycoside. (D.I. 234 at 14-15.) Sicor also claims that the prosecution history affirms this reading of the patent. (*Id.* at 16-17.) Pharmacia argues that Sicor's proposed definition is improper because it imports a limitation from the specification into the claims, because the prosecution history "irrefutably rebuts" Sicor's definition, and

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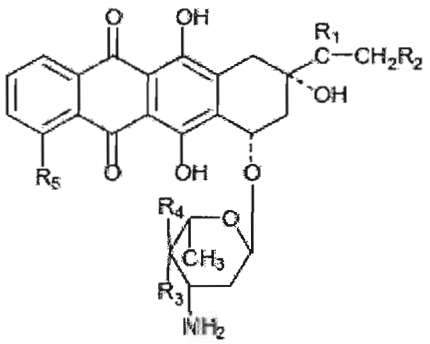
[5] The parties agree that anthracycline glycoside has the following generic chemical structure:



because nothing in the specification or prosecution history supports Sicor's arguments. (*Id.* at 25-28.)

b. The Court's Construction

The debate between the parties centers on whether "anthracycline glycoside," as that term is used in the patent, must be a non-lyophilized preparation of that chemical compound, or whether lyophilized preparations of the compound are included in what is claimed. Each of the prior applications and patents in the '285 patent family had claims containing the limitation "has not been reconstituted from a lyophilizate." (*See* U.S. Patent Application 878,784, D.I. 232, Ex. 4 at PI775-77; U.S. Patent No. 4,946,831 (issued Aug. 7, 1990), D.I. 232, Ex. 11 at 20:41-42; '856 Application, D.I. 232, Ex. 14 at PI 191-93.) When the '742 application was initially filed as a divisional of the '856 application, it also contained that limitation. (D.I. 232, Ex. 17 at PU 0014911-13.) In fact, the applicant used the lyophilization requirement to distinguish a piece of prior art relied on by the examiner, stating that "[t]he recitation of a sealed container, together with the requirement that the solution has not been reconstituted from a lyophilizate, effectively distinguishes Baurain et al." (D.I. 235, Ex. I at PU 0015609.)

The examiner, however, directly addressed this argument, and found that that argument "has not been found persuasive because a lyophilizate which is reconstituted in water [has] not been [found] to be patentably distinct from an unlyophilized solution." (D.I. 235, Ex. I at PU 0015077.) The applicant responded by removing the language "has not been reconstituted from a lyophilizate" from the claims of the '285 patent, stating:

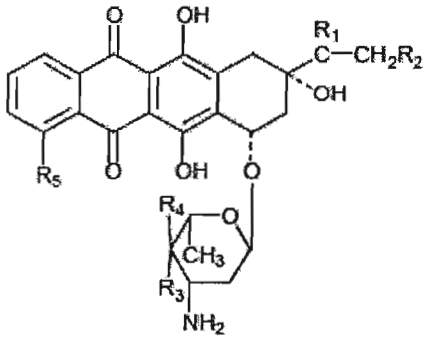
> The Claims of this application were previously drafted in a way that distinguished Applicants' solutions from certain prior art products which are reconstituted from lyophilizate powder in vials by medical personnel at the time of drug administration. The comments of the Examiner in the last Office Action indicated that whether the solution was reconstituted from lyophilizate is immaterial because patentability must reflect the inherent properties of the claimed solution and the prior art. Consistent with the Examiner's comments, [the claims] are now amended (by deleting the lyophilizate limitation) to show the important and *claimed* properties of the present invention do arise from the inherent properties of the solution, regardless of whether the solution is prepared from lyophilizates in vials.

(D.I. 232, Ex. 22 at PU 0015157 (emphasis in original).) In removing the limitation "has not been reconstituted from a lyophilizate," the applicant for the '285 patent removed a limitation from the claims, expanding their scope.

That argument is reinforced by other aspects of the history of the '285 patent. If "anthracycline glycoside" was construed, as Sicor contends, to mean "has not been reconstituted from a lyophilizate," then the claims in earlier patents and patent applications in the '285 patent family were redundant. These claims included "anthracycline glycoside," and then claimed that such anthracycline glycoside "ha[d] not been reconstituted from a lyophilizate." (*See* U.S. Patent Application 878,784, D.I. 232, Ex. 4 at PI775-77; U.S. Patent No. 4,946,831 (issued Aug. 7, 1990), D.I. 232, Ex. 11 at 20:41-42; '856 Application, D.I. 232, Ex. 14 at PI 191-93; '742 Application, D.I. 232, Ex. 17 at PU 0014911-13.) Therefore, the "anthracycline glycoside" in those claims, and in the claims of the '742 application as filed, could only be read as requiring that the "anthracycline glycoside" was a non-lyophilized form of that compound if the later language expressly stating that limitation were read as being entirely redundant. By removing the limitation "has not been reconstituted from a lyophilizate" from the claims, the applicant broadened the scope of the claims of the '285 patent.

Sicor argues that, by removing this limitation, Pharmacia did not broaden its claims, but simply removed a limitation that the patent examiner found unimportant. Furthermore, Sicor points to the repeated discussion in the written description of the patent of the problems with lyophilizing and reconstituting anthracycline glycoside, and the repeated assertions in the written description that the invention does not "require either lyophilization or reconstitution." (See '285 patent at 1:56.) Sicor is correct that Pharmacia chose to describe the invention as an anthracycline glycoside "which has not been reconstituted from a lyophilizate," ('285 patent at Abstract), and, were it not for the extensive prosecution history bearing on this point, Sicor's argument would be more persuasive, perhaps conclusively so. But the prosecution history is there, and accepting Sicor's position would require me to ignore it. On this record, Sicor's proposed construction amounts to an impermissible reading of a limitation from the specification into the claims.

Therefore, I will construe the term "anthracycline glycoside" to mean "a class of chemical compounds having the following generic structure:



."

3. "sealed"/"sealed container"

a. The Parties' Proposed Constructions

Pharmacia asserts that "sealed container" means "[a] closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed[.]" (D.I. 232 at 28.) In support of its proposed construction, Pharmacia cites the specification of the patent, which describes both "closing" and "sealing" the container, as well as the prosecution history of the patent and the statements of witnesses. (*Id.* at 28-31.) Sicor, on the other hand, argues that the term "sealed" means "closed in some fashion such that it does not allow the passage of the solution." (D.I. 234 at 18.) Sicor cites to the language of the specification in support of its construction, and argues that Pharmacia is improperly attempting to import a limitation from the preferred embodiment into the claims by its definition. (*Id.* at 18-19.) Sicor also cites to the prosecution history of the patent and to what it asserts is the ordinary meaning of the term "sealed." (*Id.* at 19-21.)

b. The Court's Construction

The ordinary meaning of the term "sealed" is different from, and encompasses something more than, the ordinary meaning of the term "closed." For example, the definitions of "sealed" cited by Sicor in its claim construction brief define "sealed" to mean "anything that tightly or completely closes or secures a thing ... to close by any form of fastening that must be broken before access can be gained" (D.I. 235, Ex. M (*Random House Dictionary of the English Language* 1286 (1983))), and "an airtight closure ... to close hermetically" (*id.* at Ex. O (*The American Heritage Dictionary* 1105 (2d College ed. 1982))). Thus, based on the ordinary meaning of the term "sealed,"

even accepting Sicor's authorities, Sicor's definition must fail, since Sicor essentially equates "sealed" with "closed."

That "sealed" means something more than "closed" is confirmed by the specification of the patent, which repeatedly states that "[t]he vials were then closed with ... rubber stoppers and sealed with aluminum caps." ('285 patent at 6:8-10; *see also id.* at 7:1-3; *id.* at 8:32-34; *id.* at 9:27-29; *id.* at 10: 30-32.) In fact, the patent uses language like this fourteen times, which contrasts something"closed" with something "sealed." The prosecution history further supports Pharmacia's definition of "sealed," as it states on at least four separate occasions the significance of the container being sealed. (*See* D.I. 232, Ex. 5 at PI 844; *id.*, Ex. 6 at PI 877; *id.*, Ex. 7 at PI 928; *id.*, Ex. 31 at PU 15057.)

Thus, I will construe the term "sealed container," as Pharmacia proposes, to mean "a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed."

4. "storage stability"

a. The Parties' Proposed Constructions

The term "storage stability" appears only in claim 9 of the '285 patent. The parties agree that "storage stability" should be defined to require 90% potency for a period of time, but they dispute what that time period is, and whether the solution must remain "physiologically acceptable" during that time period. (D.I. 232 at 32-37; D.I. 234 at 21-22.) Pharmacia asserts that "storage stability" should be defined to mean "retaining physiological acceptability and at least 90% potency for at least 18 months." (D.I. 232 at 32.) In support of that construction, Pharmacia cites the first thirteen

experiments described in the patent specification, as well as statements in the prosecution history and expert testimony on the ordinary meaning of that term. (*Id.* at 32-37.) Sicor, however, asserts that "storage stability" should be construed to mean that "at least 90% of the original amount of anthracycline glycoside dissolved in solution remains in the solution when stored at a temperature of about 4°C or 8°C for a period of at least 180 days." (D.I. 234 at 23.) Sicor relies on the specification of the patent, and particularly on the fourteenth example, in support of its construction. (*Id.* at 21-22.)

b. The Court's Construction

The parties first dispute revolves around whether "storage stability" requires 90% potency for 180 days or 18 months. The only direct statement regarding the length of time required for storage stability in the intrinsic evidence comes from the prosecution history. During prosecution of the patent, the applicant stated in a declaration filed by one of the inventors that "the stability at 22°C of doxorubicin HCl dissolved at 2 mg per ml diluted hydrochloric acid pH 3.0 is higher than the stability at 22°C of doxorubicin HCl dissolved at 2 mg per ml 0.06 M phosphate buffer pH 3.0 and 6.0, and can reach 18 months at a storage temperature between 2 and 8°C[.]" (D.I. 232, Ex. 8 at PI 939.) This statement suggests that the applicants expected stability for a period of 18 months when prosecuting the patent.

The examples provided in the specification also support a construction of "storage stability" that requires stability for 18 months. Examples 2-13 show, through extrapolation of data, that when the claimed solution is stored at either 4°C or 8°C, it is stable for at least 18 months. ('285 patent at cols. 6-21, examples 2-13.) In each of these twelve examples, the percent potency was measured at four, eight or twelve

weeks. (*Id.*) That data was then used to extrapolate at what point in time the potency of each sample would reach 90%, a time point which is referred to in the patent as t_{90}. (*Id.*) In all but one of these examples,[6] t_{90} at both 4°C and 8°C was greater than 18 months. (*Id.*) Furthermore, even without extrapolating from the actual data, in examples 2, 3, and 8, at twelve weeks (84 days) of storage at 4°C, the solutions were 99%, 98.7%, and 98.1% potent, respectively. (*Id.*) All of this data indicates that "storage stability," as it is used in the patent, requires 90% potency for longer than the 180 days that Sicor suggests, and closer to the 18 months that Pharmacia argues.

Additionally, in Example 14 of the patent, stability of the solution was measured at one, three, and six months when it was stored at 4°C and 8°C. (*Id.* at col. 22, table 14.) At 4°C, after six months, the solution still contained 98.7% of the initial doxorubicin concentration. (*Id.*) At 8°C, 98.2% remained. (*Id.*) Because, in both of these instances, far more than 90% of the doxorubicin remained in the solution after six months, or 180 days, both of these figures suggest that the t_{90} of the solution is longer than the 180 days that Sicor suggests. Because the available data suggest that t_{90} is longer than 180 days, and because the only number that appears anywhere in the intrinsic evidence is 18 months in the prosecution history, I will construe "storage stability" to require 90% potency for at least 18 months.

The parties also dispute whether the solution must remain "physiologically acceptable." Because claim 9 depends from claim 1, the preamble of claim 9, when re-written as an independent claim, reads "[a] physiologically acceptable solution of

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[6] In example 9, t_{90} was 505 days, or approximately 16.8 months, at 8°C. ('285 patent, col. 16, example 9.)

anthracycline glycoside... ." ('285 patent at 23:5-6.) Thus, while the term "storage stability" does not specifically require that the solution remain "physiologically acceptable," the claim itself requires a "physiologically acceptable solution." Therefore, I will not include this particular limitation in the construction of this term, and I will construe the term "storage stability" to mean "retaining at least 90% potency for at least 18 months."

B. *Summary Judgment Motions*

1. Non-Infringement

Sicor's Motion for Non-Infringement is founded on my adopting its construction of "anthracycline glycoside," which required that term to include only non-lyophilized preparations of the compound. (D.I. 247 at 7-9.) Because I have construed that term only to require a class of chemical compounds having a particular general structure, Sicor's Motion for Summary Judgment of Non-Infringement (D.I. 246) will be denied.

2. Invalidity for Lack of Written Description

Sicor has also moved, in the alternative, for summary judgment that the '285 patent is invalid for lack of written description under Pharmacia's claim construction of "anthracycline glycoside." (D.I. 246.) Sicor asserts that under Pharmacia's definition of that term, such that the drug can be in either lyophilized or non-lyophilized form, the written description of the patent, which consistently emphasizes the problems with lyophilization and reconstitution, does not support a lyophilized anthracycline glycoside being used in the patented solution. (D.I. 247 at 10, 12-17.) Pharmacia asserts, on the other hand, that Sicor has provided no facts, only attorney argument, in support of its contentions, and thus that Sicor's summary judgment motion should be denied.

"[T]he issue of whether the written description requirement has been satisfied is a question of fact." *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998). Pharmacia claims that Sicor has no evidence that the written description of the '285 patent is insufficient to support the claims under my construction of "anthracycline glycoside." (D.I. 262 at 14.) However, Sicor has presented evidence both of the written description of the patent itself (*see* D.I. 247 at 14-16), and has also presented expert testimony regarding what one of ordinary skill in the art would understand the invention of the '285 patent to be based on the written description," (D.I. 269, Ex. 14 at 13).

The written description requirement requires that the invention be described such that it is clear that the applicant invented what is claimed. "The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses only that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding." *In re Benno*, 768 F.2d 1340, 1346 (Fed. Cir. 1985). Therefore, even though the claims of the '285 patent are broad enough to encompass both non-lyophilized and lyophilized preparations of anthracycline glycoside, the written description must support both of these in order for the patent to be valid.[7]

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[7] The written description of the '285 patent repeatedly describes a non-lyophilized anthracycline glycoside. The abstract of the patent states that the invention provides "a sterile, pyrogen-free, ready-to-use solution of an anthracycline glycoside . . . which as not been reconstituted from a lyophilizate." ('285 patent Abstract.) The written description of the invention repeatedly states that the invention "does not require either lyophilization or reconstitution" or that the invention has "not been reconstituted from a lyophilizate." ('285 patent at 1:56; *id.* at 1:61-62; *id.* at 3:30-31; *id.* at 3:66 ("salt is not in the form of a lyophilizate").) Additionally, the patent touts the advantages of not lyophilizing anthracycline glycoside or reconstituting it from a lyophilizate. The patent states:

The '285 patent never discusses the use of a lyophilized preparation of anthracycline glycoside, and gives no examples where such a preparation is used. In fact, the '285 patent repeatedly touts the advantages of not lyophilizing anthracycline glycoside in making the claimed solution. (*See supra* at note 7.) Therefore, there is a strong case to be made, based on the language of the patent, that the use of a lyophilized anthracycline is not described in the '285 patent.

Sicor's expert came to this conclusion, stating in his report that "[g]iven the patent's criticism of lyophilized product, it is my opinion that the '285 patent would be

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> At present, anthracycline glycoside antitumor drugs ... are solely available in the form of lyophilized preparations, which need to be Reconstituted before administration.
>
> Both the manufacturing and the reconstitution of such preparations expose the involved personnel (workers, pharmacists, medical personnel, nurses) to risks of contamination which are particularly serious due to the toxicity of the antitumor substances.

(*Id.* at 1:24-32.)

The patent then goes on to say that the invention does not "require either lyophilization or reconstitution." (*Id.* at 1:56.) Later, the patent describes the invention as having "a great advantage over the presently available lyophilized preparates" because of the problems with reconstitution and difficulty obtaining high concentrations of the drug in solution. (*Id.* at 4:9-10.) Thus, the patent describes the problems with both lyophilization and reconstitution of anthracycline glycoside, and states that the invention of the '285 patent solves some of those problems by providing anthracycline glycoside in solution.

The prosecution history of the patent also has many references to lyophilization. When the '742 application was initially filed as a divisional of the '856 application, it contained the limitation "has not been reconstituted from a lyophilizate." (D.I. 232, Ex. 17 at PU 0014911-13.) All prior applications and patents in same family as the '285 patent similarly contained this limitation. (*See* U.S. Patent Application 878,784, D.I. 232, Ex. 4 at PI775-77; U.S. Patent No. 4,946,831 (issued Aug. 7, 1990), D.I. 232, Ex. 11 at 20:41-42; '856 Application, D.I. 232, Ex. 14 at PI 191-93.)

Thus, the disclosure of the invention, as well as the invention described in prior patent applications in the same family, limited the invention to a non-lyophilized anthracycline glycoside. Why, in the face of the foregoing, the examiner allowed the applicant to broaden the scope of the claims of the '285 patent by removing the limitation "has not been reconstituted from a lyophilizate" is, to say the least, puzzling.

understood by 'those of ordinary skill in the art' to describe an invention in which avoiding a lyophilizate in manufacturing or administering anthracycline glycoside is an essential feature of the invention." (D.I. 269, Ex. 14 at 13.) Not surprisingly, Pharmacia's expert takes the opposite position, stating that, in his understanding, "one of ordinary skill in the art would not have understood the terms 'lyophilizate' and 'reconstitution' ... to be limitations on the claims of the '285 patent." (D.I. 263, Ex. 11 at 30.) And it is true that the claim itself contains no such limitation. On a motion summary judgment I "may not make credibility determinations or weigh the evidence." *Reeves*, 530 U.S. at 150. Therefore, because these experts disagree about what one of ordinary skill in the art, looking at the written description, would have understood the scope of the claims to be, there are genuine issues of material fact on whether the written description of the '285 patent is sufficient to support the claims. Accordingly, Sicor's Motion for Summary Judgment that the '285 Patent is Invalid for Lack of Written Description (D.I. 246) will be denied.

3. Anticipation

The parties have cross-moved for summary judgment on anticipation. (D.I. 252, 254.) The motions of both parties can be resolved by my construction of the term "sealed container," which I construed, as Pharmacia contended, to mean "a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed." (*See supra* at section IV.A.3.b.)

Sicor asserts that a 1985 article entitled "Doxorubicin decomposition on storage. Effect of pH, type of buffer and liposome encapsulation" written by M.J.H. Janssen et al.

("Janssen") anticipates the '285 patent. (D.I. 255, Ex. A). However, with respect to Janssen, Sicor stated in its briefing that "Sicor does not contest that, under Pharmacia's . . . claim construction [of the term sealed container], Janssen does not disclose a sealed container." (D.I. 212 at 12.) Because I have adopted Pharmacia's construction, there is no genuine issue of material fact that Janssen does not anticipate claim 1 of the '285 patent, because it does not disclose a sealed container. Thus, summary judgment of no anticipation will be granted to Pharmacia as to the Janssen reference.

Sicor also asserts that, if I construe the term "anthracycline glycoside" to include both lyophilized and non-lyophilized forms of the drug, two additional references anticipate the invention of the '285 patent. These references are a December, 1981 article published in the American Journal of Hospital Pharmacy entitled "Stability and Compatibility of Antitumor Agents in Glass and Plastic Containers" written by John A. Benvenuto et al. ("Benvenuto"), and the product used in the experiments described in that paper, Pharmacia's Adriamycin® (doxorubicin hydrochloride) for Injection ("Adriamycin"). (D.I. 255 at 9-14.) Because I have construed "anthracycline glycoside" such that it is not limited to the non-lyophilized form of the drug, I will address Sicor's anticipation arguments regarding these two references.[8]

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[8] Pharmacia argues that Sicor should be barred from relying on Benvenuto or Adriamycin, because "Sicor hid its anticipation contentions [and] . . . never identified the Benvenuto reference and reconstituted Adriamycin as potentially anticipatory art." (D.I. 260 at 17-18.) Pharmacia also asserts that Sicor knew about these references at least since they were identified by Sicor's opinion counsel in a letter Sicor obtained on February 28, 2001. (*Id.*) Pharmacia is correct that, in response to its contention interrogatory, which asked Sicor to "describe in detail each factual and legal basis for Sicor's contention that the '285 patent is invalid under 35 U.S.C. §§ 101 & 102 ...[,]" Sicor did not identify Benvenuto or Adriamycin. (*See* D.I. 261 at Ex. 6, 7.) Sicor does not contend otherwise. Sicor argues that the contention interrogatory only required it to

Sicor asserts that Benvenuto contains all of the limitations of the '285 patent, and thus anticipates it. (D.I. 255, Ex. B.) With respect to the containers in Benvenuto being "sealed," the article states that "[d]rugs were reconstituted ... and resulting solutions were added to 50 ml 5% Dextrose Injection, USP, in plastic bags (Viaflex, polyvinyl chloride, . . .) and glass containers[.]" (*Id.* at 1914.) Sicor seems to assert that, by necessity, these bags and containers were sealed, and that this is sufficient to show this element of the claim. I disagree. There are genuine issues of material fact that remain as to whether the plastic bags and glass containers used in Benvenuto were "secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed." Sicor thus cannot show, at this stage of the case, that Benvenuto anticipates the invention of the '285 patent. Summary judgment that Benvenuto anticipates the '285 patent will accordingly be denied.

Sicor's arguments on anticipation by Adriamycin likewise fail. Sicor asserts that according to a handbook written by Lawrence A. Trissel, *Handbook on Injectable Drugs* (3d ed. 1983), Adriamycin was reconstituted with water, and then shaken so that the drug could dissolve. (D.I. 255, Ex. C at 171.) Sicor argues that the fact that the

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disclose references that were anticipating under its own claim construction, and that because both the product in the Benvenuto reference and Adriamycin are lyophilized, these references did not have to be disclosed. (D.I. 272 at 6-7.) Sicor also asserts that it produced its February 2001 opinion of counsel, which gave Pharmacia sufficient notice that Sicor intended to assert Benvenuto and Adriamycin as anticipatory prior art. (*Id.*)

Sicor's argument is tenuous, considering the clear language of the interrogatory and the fact that Sicor's expert report does not discuss any anticipatory references other than Janssen (D.I. 261, Ex. 10 at 16). However, I will not rule on the exclusion of these references at this time, and will consider Pharmacia's argument for exclusion if an appropriate motion in limine is filed.

solution should be shaken "necessarily mean[s] that the solution is in a sealed container so as to minimize exposure and maintain sterility." (D.I. 255 at 13.) Leaving aside the fact that Sicor relies on both Adriamycin itself and the handbook, rather than a single reference, as is required for anticipation, there remain genuine issues of material fact as to whether Adriamycin is in a "sealed container," as I have defined that term here. Therefore, Sicor's motion for summary judgment on anticipation based on Adriamycin is also denied.[9]

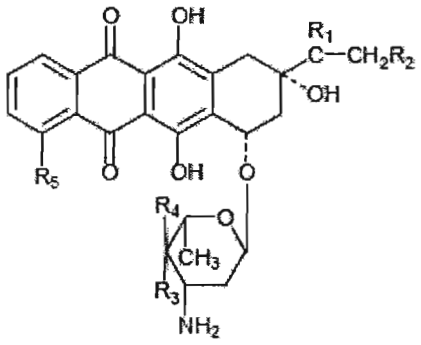
4. Unclean Hands

Pharmacia has also moved for summary judgment on Sicor's Unclean Hands Affirmative Defense. (D.I. 248.) Pharmacia's argument that it should be granted summary judgment on this issue comes down to an assertion that Sicor did not make proper disclosures regarding this defense in its contention interrogatories, and that Sicor should not be able to modify those answers at this stage of the litigation. (D.I. 249 at 7.) While that may or may not be true, this motion is really a motion to exclude evidence, and is properly dealt with as a motion in limine. I therefore decline to deal with the substance of the motion at this stage of the case, and will deny Pharmacia's Motion for Summary Judgment on Sicor's Unclean Hands Defense, without prejudice to any argument it may make in a motion in limine.

[9] Pharmacia's Motion for Summary Judgment on Anticipation (D.I. 252) only addresses anticipation by the Janssen reference.

V. CONCLUSION

Accordingly, for the foregoing reasons, the disputed claim terms will be construed as follows:

Claim Term	The Court's Construction
"physiologically acceptable"	The court construes the term "physiologically acceptable" to mean "the substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals."
"anthracycline glycoside"	The court construes the term "anthracycline glycoside to mean "a class of chemical compounds having the following generic structure:  ."
"sealed container"	The court construes the term "sealed container" to mean "a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed."
"storage stability"	The court construes the term "storage stability" to mean "retaining at least 90% potency for at least 18 months."

Additionally, Sicor's Motion for Summary Judgment of Non-Infringement (D.I. 246) will be denied, and its alternative Motion for Summary Judgment of Invalidity for

Lack of Written Description (D.I. 246) will also be denied. Pharmacia's Motion for Summary Judgment on Sicor's Anticipation Affirmative Defense (D.I. 252) will be granted as to the Janssen reference, and Sicor's Motion for Summary Judgment of Anticipation (D.I. 254) will be denied. Pharmacia's Motion for Summary Judgment on Sicor's Unclean Hands Affirmative Defense (D.I. 248) will also be denied. An appropriate order will follow.

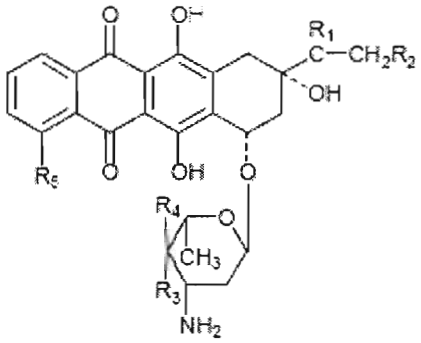
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACIA & UPJOHN COMPANY, Plaintiff, v. SICOR INC. AND SICOR PHARMACEUTICALS, INC., Defendants.	)	Civil Action No. 04-833 (KAJ)

ORDER

For the reasons set forth in the Memorandum Opinion issued today, IT IS HEREBY ORDERED that the following disputed claim terms of U.S. Patent No. 6,107,285 (issued August 22, 2000) are construed as follows:

Claim Term	**The Court's Construction**
"physiologically acceptable"	The court construes the term "physiologically acceptable" to mean "the substance is sterile, pyrogen-free, and otherwise suitable for administration to humans or animals."

"anthracycline glycoside"	The court construes the term "anthracycline glycoside to mean "a class of chemical compounds having the following generic structure:  ."
"sealed container"	The court construes the term "sealed container" to mean "a closed container which is further secured against access, leakage and passage by a fastening, membrane, or coating that must be broken to be removed."
"storage stability"	The court construes the term "storage stability" to mean "retaining at least 90% potency for at least 18 months."

IT IS FURTHER ORDERED that the Motion for Summary Judgment of Non-Infringement filed by Sicor Inc. and Sicor Pharmaceuticals, Inc., ("Sicor") (Docket Item ["D.I."] 246) is DENIED, and Sicor's alternative Motion for Summary Judgment of Invalidity for Lack of Written Description (D.I. 246) is also DENIED.

IT IS FURTHER ORDERED that the Motion for Summary Judgment on Sicor's Anticipation Affirmative Defense (D.I. 252) filed by Pharmacia & Upjohn Company ("Pharmacia") is GRANTED as to the Janssen reference, and Sicor's Motion for Summary Judgment of Anticipation (D.I. 254) is DENIED.

IT IS FURTHER ORDERED that Pharmacia's Motion for Summary Judgment on Sicor's Unclean Hands Affirmative Defense (D.I. 248) is DENIED.

IT IS FURTHER ORDERED that, within five days, the parties will provide recommendations for redactions to this opinion so that a public version may be filed. Proposed redactions must be kept to an absolute minimum

UNITED STATES DISTRICT JUDGE

August 17, 2006
Wilmington, Delaware