

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LABORATORY SKIN CARE, INC.
and ZAHRA MANSOURI,

Plaintiffs,

v.

Civil Action No. 06-601-LPS

LIMITED BRANDS, INC.
and BATH AND BODY WORKS, LLC,

Defendants.

E. Anthony Figg, Esquire, Sharon L. Davis, Esquire, C. Nichole Gifford, Esquire, and Daniel Shores, Esquire of ROTHWELL, FIGG, ERNST & MANBECK PC, Washington, D.C.
Josy W. Ingersoll, Esquire, Melanie K. Sharp, Esquire, and Karen E. Keller, Esquire of YOUNG CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware.

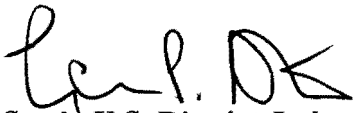
Attorneys for Plaintiffs.

John F. Ward, Esquire, David M. Hill, Esquire, and Michael J. Zinna, Esquire of WARD & OLIVO, New York, New York.
Francis G.X. Pileggi, Esquire and Sheldon K. Rennie, Esquire of FOX ROTHSCHILD LLP, Wilmington, Delaware.

Attorneys for Defendants.

MEMORANDUM OPINION

December 6, 2010
Wilmington, Delaware.


Stark, U.S. District Judge:

Pending before the Court are Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 102(b) (D.I. 125), the remaining portion of Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 102 (D.I. 128) related to the relevant Solarcaine® products, Plaintiffs' Motion for Leave to File a Sur-Reply Brief in Response to Defendants' Reply Brief in Support of Their Motion for Summary Judgment of Invalidity Under 35 U.S.C. §102(b) (D.I. 239), Plaintiffs' Motion to Preclude Defendants from Relying on Documents Identified for the First Time in Their Reply Brief (D.I. 245), and Defendants' Motion to Bifurcate Liability Issues from Damages and Willfulness Issues (D.I. 289).

For the reasons discussed, the Court will grant Plaintiffs' Motion to Preclude Defendants From Relying on Documents Identified for the First Time in Their Reply Brief (D.I. 245) and Defendants' Motion to Bifurcate Liability Issues from Damages and Willfulness Issues (D.I. 289), but will deny the other three Motions.

I. BACKGROUND

This is a patent infringement case brought by Plaintiffs Laboratory Skin Care, LLC and Zahra Mansouri ("Plaintiffs") against Defendants Limited Brands, Inc. and Bath and Body Works, LLC ("Defendants") alleging infringement of United States Patent No. 6,579,516 ("the '516 patent"), which pertains to formulations for skin cleansers and moisturizers. Although Plaintiffs filed the application that resulted in the '516 patent on November 28, 2000, the '516 patent traces its priority to an earlier June 13, 1995 application. '516 Patent, col. 1 lines 5-15.

Plaintiffs filed their Complaint (D.I. 1) on September 26, 2006. Defendants filed their Answer with Counterclaim (D.I. 10) on October 19, 2006. On December 5, 2006, the Court

issued a Scheduling Order (D.I. 21) requiring the parties to file amended pleadings by June 28, 2007 and discovery to end on October 5, 2007. The Court subsequently amended the Scheduling Order (*see* D.I. 57) to extend the deadline for document discovery to June 11, 2008, depositions to August 11, 2008, and dispositive motions to September 10, 2008. Neither party filed amended pleadings. On September 10, 2008, Defendants filed two motions for summary judgment of invalidity, alleging the '516 patent is invalid as anticipated (D.I. 128) and that it is invalid pursuant to the on-sale bar of 35 U.S.C. § 102(b) (D.I. 125).

The Court addressed both of Defendants' summary judgment motions in a Memorandum Opinion and Order issued on October 14, 2009. (D.I. 217, 218) There, the Court ordered full briefing on Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 102(b) (D.I. 125) and denied Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 102 as it related to anticipation (D.I. 128), but required the parties to submit additional briefing on whether the Solarcaine® products constitute anticipatory prior art to the patent-in-suit (D.I. 218).

Following the Court's October 14, 2009 Order, both parties submitted briefs on the issues of the on-sale bar and anticipation by the Solarcaine® products. In response to Defendants' Reply Briefs (D.I. 232, 235), Plaintiffs filed two additional motions: a November 24, 2009 Motion for Leave to File a Sur-Reply Brief in Response to Defendants' Reply Brief in Support of their Motion for Summary Judgment of Invalidity Under 35 U.S.C. §102(b) (D.I. 239), and a December 8, 2009 Motion to Preclude Defendants from Relying on Documents Identified for the First Time in Their Reply Brief (D.I. 245). On October 27, 2010, Defendants filed a Motion to Bifurcate Liability Issues from Damages and Willfulness Issues. (D.I. 289)

II. LEGAL STANDARDS

A grant of summary judgment is appropriate only where “the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 415 U.S. 574, 586 n.10 (1986). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Id.* at 587 (internal quotation marks omitted). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may 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*, 475 U.S. at 586-87; *see also Podohnik v. U.S. Postal Service*, 409 F.3d 584, 594 (3d Cir. 2005) (party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). However, the “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 411 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 411 U.S.

317, 322 (1986) (entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.”).

III. MOTIONS RELATING TO THE ON-SALE BAR

A. Plaintiffs’ Motion To File A Sur-Reply Brief

Following the completed briefing of Defendants’ Motion For Summary Judgment regarding the on-sale bar, Plaintiffs filed a Motion for Leave to File a Sur-Reply Brief (D.I. 239), on the grounds that Defendants’ Reply Brief contained new arguments as well as factual errors and misrepresentations. Defendants oppose this motion. (D.I. 247) The Court denies Plaintiffs’ motion as moot based on the Court’s decision to deny Defendants’ Motion For Summary Judgment, addressed immediately below.

B. Defendants’ Motion For Summary Judgment

1. Applicable Legal Principles

In pertinent part, 35 U.S.C. § 102(b) (2006) states that “[a] person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of application for patent in the United States.” To trigger the on-sale bar under Section 102(b), the alleged infringer must prove that the product sold “fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art.” *Allen Eng. Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1352 (Fed. Cir. 2002) (internal citations omitted). Therefore, an accused infringer must show that the product offered for sale “embodied all of the limitations of that claim or would have rendered that claim obvious.” *Id.* In addition, the accused infringer must establish by clear and convincing evidence that, before the critical date,

(1) the product was the subject of a commercial offer for sale and (2) the invention was ready for patenting. *See Pfaff v. Wells Elecs.*, 525 U.S. 55, 67 (1998). Under the first element of *Pfaff*, courts must determine whether there has been a commercial offer for sale by “applying traditional contract law principles.” *Allen*, 299 F.3d at 1352. This first element may be further broken down into a two-step analysis. The Court must determine, first, whether there was a commercial offer for sale, and, second, whether that offer was for the patented invention. *See Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001). The second element of *Pfaff*, the “ready for patenting” requirement, “may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.” *Pfaff*, 525 U.S. at 67-68.

2. Parties’ Contentions

Defendants argue that Plaintiffs sold an embodiment of the claimed invention before the June 13, 1994 critical date, invalidating the asserted claims pursuant to the on-sale bar of 35 U.S.C. § 102(b).¹ Specifically, Defendants contend that Plaintiffs provided manufacturer Francosmetics International, Inc. (“Francosmetics”) a moisturizer formulation sheet and processing instructions for preparing embodiments of the claimed invention. (D.I. 126 at 11) Defendants further allege that, after Francosmetics produced the moisturizer (“the Francosmetics Product”), Plaintiffs sold it to distributors Baxter Scientific Products (“Baxter”) and Paxxis, Inc.

¹The priority date for the ‘516 patent is June 13, 1995. Accordingly, the critical date for the purposes of the on-sale bar is June 13, 1994. *See* 35 U.S.C. § 102(b) (“A person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of application for patent in the United States.”).

("Paxxis"). (*Id.* at 13-14)

In response, Plaintiffs assert that the Francosmetics Product was contaminated. Because of this contamination, Plaintiffs contend, the moisturizer did not contain "an amount of triclosan effective to kill microorganisms on the skin," an element of Claims 1 and 12 of the '516 patent. (D.I. 160 at ¶ 3) Since the product sold did not contain every element of Claims 1 and 12, the sales, according to Plaintiffs, did not trigger the on-sale bar. In addition to Francosmetics' alleged inability to produce an embodiment of the claimed moisturizer, Plaintiffs assert that two other manufactures, Libby Laboratories Inc. ("Libby") and Gordon Laboratories Inc. ("Gordon"), were unable to produce an embodiment of the patented moisturizer prior to June 13, 1994.² (*Id.* at ¶ 9) This, Plaintiffs contend, further demonstrates the invention was not ready for patenting at the time the offer was made to Baxter and Paxxis, creating a genuine issue on the second element of the *Pfaff* test. (D.I. 224 at 9)

Defendants reply that the invention was ready for patenting by the critical date, pointing out that a company Plaintiffs hired to develop the lotion, Cosmetic Technologies, successfully prepared samples that were antimicrobial. (D.I. 235 at 4) Defendants also assert that Plaintiffs conceded prior sales in a proceeding before the United States Patent and Trademark Office ("PTO"). (*Id.*)

3. Decision

To resolve Defendants' Summary Judgment Motion, the Court considers the two elements

²In their Reply Brief in support of their Motion For Summary Judgment, Defendants state that they rely only on the alleged offers to sell the products manufactured by Francosmetics. (D.I. 165 at 7) ("The Limited Defendants' Opening Brief does not even mention – much less rely on – any facts surrounding the work performed by Libby or Gordon.")

of the *Pfaff* test.

a. Commercial Offer For Sale

Both sides agree that Plaintiffs sold a moisturizer product before the critical date. There is documentation of several sales of “LSC Moisturizer” before June 1994, including to Francosmetics. (*See* D.I. 132 Ex. I) Clearly, Plaintiffs made a commercial offer for sale.

But, to assist Defendants, the offer must have been for the patented invention. *See Scaltech*, 269 F.3d at 1330. On this issue, there is a genuine dispute of fact. The parties disagree on whether the Francosmetics Product was an embodiment of the claimed invention. Plaintiffs argue that the Francosmetics Product failed to meet the limitations of the asserted claims because it was contaminated and not “an effective antimicrobial lotion.” (D.I. 224 at 18) Defendants argue it was an embodiment of the claimed invention because it passed testing and inspection, and the evidence to the contrary – Ms. Mansouri’s declarations to the PTO and deposition testimony – lacks merit. (D.I. 235 at 8-9)

Both sides present evidence in their favor regarding the quality of the Francosmetics Product. A fact-finder will have to weigh the competing evidence. Ms. Mansouri’s testimony that the Francosmetics Product was defective cannot be discredited as a matter of law, as Defendants request. Moreover, Plaintiffs have presented evidence that Ms. Mansouri made consistent statements to the PTO regarding the defective nature of the products. Additionally, alleged offers to sell were made at two trade shows, but Defendants do not establish what representations Plaintiffs made to potential customers at these shows. In short, Defendants have failed to show that there is no genuine issue of fact regarding the first element of the *Pfaff* test.

b. Invention Ready For Patenting

To successfully raise an on-sale bar defense, Defendants must also show that the invention was ready for patenting at the time of the sale. An invention is ready for patenting when there is “proof of reduction to practice before the critical date” or “that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention.” *Pfaff*, 525 U.S. at 67-68. Both sides present evidence sufficient to create a genuine dispute on the “ready for patenting” requirement, which is a material fact.

Defendants offer evidence that Plaintiffs successfully produced the claimed invention in the development process and that the formula used by Francosmetics was later used successfully by a different manufacturer. (D.I. 237 Exs. P, Q) But Plaintiffs present evidence in their favor as well. They adduce evidence that the Francosmetics Product – the only one commercially produced prior to the critical date – was defective (D.I. 224 Exs. E, F, G, J, K, L, M), creating a genuine dispute on reduction to practice prior to the critical date.

Defendants also fail to show no genuine issue exists as to whether the formulation sheet Plaintiffs provided to Francosmetics was “sufficiently specific to enable a person skilled in the art to practice the invention.” Defendants argue this recipe was eventually used successfully, but Plaintiffs respond with evidence that three cosmetics companies – Francosmetics, Libby, and Gordon – were unable to produce the claimed invention with this recipe prior to the critical date. (D.I. 224 at 5) These failed attempts could lead a reasonable fact-finder to conclude that the invention was not ready for patenting at the time of the sale. The Court, therefore, will deny Defendants’ Motion for Summary Judgment pursuant to the on-sale bar of 35 U.S.C. § 102(b).

IV. PARTIES' MOTIONS RELATING TO ANTICIPATION BY SOLARCAINE®

A. Plaintiffs' Motion To Preclude

Following the completed briefing on anticipation by the Solarcaine® products, Plaintiffs filed a Motion to Preclude Defendants from Relying on Documents Identified for the First Time in Their Reply Brief. (D.I. 245) The evidence in question is: (1) the Second Declaration of Jack Nelson, (2) new Schering-Plough Documents marked SP0008-SP0072 ("the Additional Schering Documents"), (3) paragraphs 10-12 of the Declaration of Dr. Robert Y. Lochhead, and (4) the Solarcaine® trademark prosecution file history. (D.I. 245 at 1) Each of these items was first presented in Defendants' Reply Brief. (D.I. 232)

1. Applicable Legal Principles

Rule 7.1.3(c)(2) of the Local Rules of the United States District Court for the District of Delaware ("D. Del. LR") states "[t]he party filing the opening brief shall not reserve material for the reply brief which should have been included in a full and fair opening brief." Sanctions may be imposed for violations of the local rules pursuant to D. Del. LR 1.3(a), which states "[s]anctions may be imposed, at the discretion of the Court, for violations of the Rules, as well as for violations of the Fed. R. Civ. P. and any order of the Court. Such sanctions may include, but are not limited to, costs, fines and attorneys' fees imposed on the offending party and that party's attorney."

2. Parties' Contentions

Plaintiffs contend that Defendants' reliance on new evidence in their Reply Brief is improper, especially since Defendants previously supplemented their Opening Brief.³ Plaintiffs argue that Defendants should have, at the least, included the new evidence in the supplemental opening brief allowed by this Court. (D.I. 246, 253) Plaintiffs assert that the tardy inclusion of new evidence and arguments are highly prejudicial and without justification. (D.I. 246, 253) Therefore, Plaintiffs allege that Defendants violated D. Del. LR 7.3.1(c)(2), which prohibits parties from "reser[ving] material for the reply brief which should have been included in a full and fair opening brief." (D.I. 246 at 13)

Defendants respond that the materials should not be precluded because: (1) Defendants received the Additional Schering Documents only one day before their Reply Brief was due, (2) the Second Declaration of Jack Nelson authenticates the Additional Schering Documents and responds to arguments made in Plaintiffs' Opposition Brief, (3) the Solarcaine® trademark prosecution history is a publicly available record and responsive to arguments made in Plaintiffs' Opposition Brief, and (4) paragraphs 10-12 of the Declaration of Dr. Robert Y. Lochhead are responsive to arguments made in Plaintiffs' Opening Brief. (D.I. 251) Therefore, Defendants argue, all the material was provided properly and in a timely manner. Defendants emphasize that they have supplemented interrogatories and provided the relevant documents to Plaintiffs in accordance with the Federal Rules of Civil Procedure ("FRCP"). (*Id.*) Defendants add that any prejudice Plaintiffs suffered was self-inflicted since they pursued no discovery from Schering-

³Defendants moved to supplement their Summary Judgment Motion on September 22, 2008. (D.I. 152) The Court granted this Motion on October 1, 2009. (D.I. 218)

Plough and failed to search publicly available records. (*Id.*)

3. Decision

The Court concludes that Plaintiffs' Motion to Preclude should be granted since Defendants violated D. Del. LR 7.1.3(c)(2). First, the Court excludes the Additional Schering Documents and the supporting Second Declaration of Mr. Jack Nelson. Although Defendants did not have this material when they filed their Opening Brief, it was their responsibility to collect all the necessary evidence relating to their defense in a timely manner. Defendants served a subpoena on Schering-Plough on August 8, 2008 (D.I. 117), when fact discovery closed on August 11, 2008 and case dispositive motions were due on September 10, 2008 (D.I. 57). Although the Court is sympathetic to Defendants' attempts to obtain discovery from Schering-Plough without resorting to a subpoena, by waiting as long as they did, Defendants ensured that they would not obtain the discovery in time. Defendants filed their Opening Brief on September 10, 2008 and on September 23, 2008 received seven documents from Schering-Plough ("the Original Schering Documents"). (*See* D.I. 152) As a result, on September 25, 2008, Defendants filed a motion to supplement their September 10, 2008 brief to include these seven documents. (D.I. 152) The Court granted the motion on October 14, 2009, allowing these seven documents and additional briefing. (D.I. 217, 218) Pursuant to this Order, Defendants filed a Reply Brief on November 19, 2009, in which, in addition to the seven documents the Court had allowed, Defendants relied on an eighth Schering-Plough document. (D.I. 234 Ex. T) Defendants also submitted the Second Declaration of Mr. Jack Nelson authenticating this additional document, as well as four other documents not included in the Original Schering Documents. (*Id.* Ex. U at ¶ 4) Subsequently, Defendants have produced a total of sixty-four documents – the Additional Schering Documents

– to Plaintiffs beyond the original seven allowed by this Court.

Although Defendants did not receive the Additional Schering Documents until November 18, 2009 (the day before their Reply Brief was due), they served Schering-Plough with its subpoena over fifteen months earlier. It was Defendants' responsibility to ensure they received a proper response to their subpoena; any delay in receiving an adequate response to the subpoena could have been brought to the attention of the Court. When Defendants approached the Court requesting to amend their Opening Brief, it was incumbent on them to account for all the necessary documents. Defendants did not file a second motion to supplement but simply included the additional documents in their Reply Brief. Under the circumstances, Defendants effectively "reserved material" by failing diligently to pursue discovery from Schering-Plough and failing to include all the necessary additional material in their Motion to Supplement, thereby violating D. Del. LR 7.1.3(c)(2). The Court, therefore, excludes all Schering documents beyond the seven Original Schering Documents allowed in the October 14, 2009 Order.

Second, the Court excludes the Solarcaine® trademark file history and the portions of expert witness Robert Y. Lochhead's declaration which rely on the file wrapper. Defendants reserved this material for their Reply Brief in violation of D. Del. LR 7.1.3(c)(2). Defendants' emphasis on the public availability of the trademark prosecution file history is misplaced; the public nature of the record cuts against them. Since it is a publicly available record, there is no reason Defendants were unable to include it in their Opening Brief. Defendants failed to locate this evidence during discovery and now ask the Court to penalize Plaintiffs by allowing the file history into evidence so late in the briefing process. The burden of raising the defense was on Defendants and they were responsible for compiling the necessary evidentiary record.

Defendants argue that the trademark file history was used to respond to Plaintiffs' Opposition Brief. (D.I. 251 at 6) But Plaintiffs, in their brief, merely asserted that Defendants failed to establish necessary elements of their defense. Plaintiffs raised no new facts which Defendants must rebut. Hence, the trademark file history and supporting declaration serve to bolster Defendants' original argument, not to respond to that of Plaintiffs. Since this evidence was not raised in Defendants' Opening Brief, Defendants' reservation of it for their Reply Brief violated D. Del. LR 7.3.1(c)(2). *See Boston Scientific Scimed, Inc. v. Cordis Corp.*, 434 F. Supp. 2d 308, 314 (D. Del. 2006) (allowing, under D. Del. LR 7.1.3(c)(2), material that was responsive to opposition's brief, but precluding testimony that was unresponsive and not previously raised); *Praxair, Inc. v. ATMI, Inc.*, 231 F.R.D. 457, 464 (D. Del. 2005) (excluding two declarations included in reply brief of alleged infringer for violating D. Del. LR 7.1.3(c)(2) because evidence was not in rebuttal of any facts presented by opposing party, but applicable only to defendant's burden on its invalidity defense).⁴

B. Defendants' Motion For Summary Judgment

1. Applicable Legal Principles

Anticipation is a question of fact. *See Upsher-Smith Labs., Inc. v. PamLab, LLC*, 412 F.3d 1319, 1322 (Fed. Cir. 2005). Nevertheless, summary judgment can be appropriate with respect to anticipation if there is no genuine issue of material fact or if, drawing all factual inferences in favor of the nonmoving party, no reasonable jury could return a verdict for the nonmoving party. *See id.*

⁴Since Defendants violated D. Del. LR 7.1.3(c)(2), it is unnecessary for the Court to consider whether, as Plaintiffs further argue (D.I. 246 at 14), Defendants also violated FRCP 26(e).

An invention is anticipated under 35 U.S.C. § 102(b) if it “was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” “A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention.” *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (internal citation omitted). Such disclosure can be explicit or inherent in the prior art. *See Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir.1991). However, mere disclosure of each and every limitation of a claim is not enough for anticipation. “An anticipating reference must enable that which it is asserted to anticipate.” *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008) (internal citations omitted). Furthermore, a single prior art reference must also disclose the limitations as arranged in the claim. *See Net Moneyin, Inc. v. Verisign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (“[U]nless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.”).

2. Parties’ Contentions

Defendants argue that summary judgment of anticipation is warranted because they have established a prima facie case of anticipation. (D.I. 232) Defendants rely on the Original Schering Documents, marked SP0001–SP0007, to argue that: (1) the formula sheets of three relevant Solarcaine® formulations contain each ingredient of the claimed invention in the proper concentrations; (2) the formulas were approved for production prior to the critical date; and (3) the formulas were on sale to the public before the critical date. (D.I. 232) Plaintiffs respond that

summary judgment of anticipation by the Solarcaine® products is improper because Defendants present no evidence that: (1) the pertinent documents – the Original Schering Documents – were printed publications; (2) the Solarcaine® products were on sale before the critical date; or (3) the Solarcaine® products were antimicrobial. (D.I. 226)

3. Decision

When the evidence is viewed in the light most favorable to Plaintiffs, there are remaining issues of material fact regarding publication of the Original Schering Documents, the sale or public availability of the Solarcaine® products prior to the critical date, and whether the Solarcaine® products met the antimicrobial limitation of the asserted claims. Summary judgment of anticipation in favor of Defendants is, therefore, improper.

Although Defendants present evidence that supports a finding of anticipation, it is not conclusive. The Original Schering Documents do not establish whether the Solarcaine® products were effective antimicrobial lotions or on sale or publicly available prior to the critical date. Further, Defendants do not establish that the Original Schering Documents themselves are prior art; all indications are that the Schering Documents were confidential, internal documents.

First, viewing the evidence in the light most favorable to Plaintiffs, the Original Schering Documents only establish that the Solarcaine® products were approved for production. Although Mr. Jack Nelson, Schering-Plough's former Manager of Formula Documentation, states that this approval indicates public sales (D.I. 188), Defendants do not conclusively establish any sale dates. A genuine factual issue therefore remains. Second, Defendants do not conclusively establish that the Solarcaine® products were antimicrobial. Although the Solarcaine® products contain the active ingredient called for by the claims in the appropriate concentration, Defendants do not

establish that the presence of this ingredient makes the products antimicrobial. Plaintiffs present credible evidence that the active ingredient, triclosan, potentially interacts with other components to render it ineffective. (*See* D.I. 226 at 4) The Court cannot discredit the testimony of Plaintiffs' witnesses, Dr. Donald Orth and Dr. Richard Wickett, as Defendants suggest. Further, Plaintiffs present a reference, *Cosmetic and Drug Preservation: Principles and Practice*, that indicates triclosan can be neutralized by other ingredients in the Solarcaine® products. (D.I. 226 Ex. 7) Defendants point out that the potentially neutralizing ingredient is also present in a preferred embodiment of the patented invention, but Defendants do not conclusively establish that the mixtures, as a whole, accounting for the dynamics between all the ingredients, would result in effective Solarcaine® products. Again, in the present procedural posture, the reasonable inferences from the record evidence must be drawn in favor of Plaintiffs.

Defendants' assertion that this Court's prior ruling supports a prima facie case of anticipation (D.I. 232 at 3) strains the scope of that decision. There, the Court merely ordered additional briefing. Further, Defendants confuse the legal standard which the Court must apply at this stage. They argue that Plaintiffs must present convincing evidence to rebut the prima facie case of invalidity Defendants allegedly establish. (*Id.*) But, to avoid summary judgment, Plaintiffs only must show that a genuine issue of material fact exists on the question of anticipation. Plaintiffs have done so.

Accordingly, Defendants' Motion For Summary Judgment of Invalidity for anticipation by Solarcaine® is denied.

V. DEFENDANTS' MOTION TO BIFURCATE

A. Applicable Legal Principles

FRCP 42(b) states that “[f]or convenience, to avoid prejudice, or to expedite and economize, the court may order a separate trial of one or more separate issues, claims, crossclaims, counterclaims, or third-party claims.” “Under Rule 42(b), a district court has broad discretion in separating issues and claims for trial as part of its wide discretion in trial management.” *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1212 (Fed. Cir. 1987). When exercising this broad discretion, courts “should consider whether bifurcation will avoid prejudice, conserve judicial resources, and enhance juror comprehension of the issues presented in the case.” *Enzo Life Scis., Inc. v. Digene Corp.*, 2003 WL 21402512, at *4 (D. Del. June 10, 2003).

B. Parties' Contentions

Defendants ask the Court to bifurcate liability issues from damages and willfulness because: (1) these issues are distinct and independent of one another; (2) a verdict of non-infringement in the first trial would obviate the need for a second trial, thus promoting judicial economy; (3) jury confusion will be reduced by focusing the jury's attention on one issue at a time; and (4) prejudice to both parties will be reduced. (D.I. 290) Plaintiffs oppose bifurcation, asserting that: (1) judicial economy will not be promoted by imposing the burden of a second trial; (2) the issues, and evidence required to resolve them, overlap; (3) the issues are not complex; and (4) Plaintiffs will be prejudiced by further delay and expense. (D.I. 292)

C. Decision

The Court finds it proper to exercise its discretion and try infringement separately from the issues of damages and willfulness. Judicial resources may be conserved through bifurcation, as liability may not be found, or even if found it may simplify the subsequent damages and willfulness trial. The burden on the jury, and risk of juror confusion, will also be reduced by trying these issues separately. Finally, although the Court is sympathetic to Plaintiffs' claim of prejudice arising from added delay, this case has already been pending more than four years, the Court will promptly (by separate Order issued today) schedule the infringement and validity trial, and the Court will proceed in a timely fashion to a subsequent trial, if necessary. Therefore, the Court grants Defendants' Motion to Bifurcate Liability Issues from Damages and Willfulness Issues.

VI. CONCLUSION

For the reasons discussed, the Court will grant Plaintiffs' Motion to Preclude Defendants from Relying on Documents Identified for the First Time in Their Reply Brief (D.I. 245) and Defendants' Motion to Bifurcate Liability Issues from Damages and Willfulness Issues (D.I. 289), but the Court will deny Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 102(b) (D.I. 125), the remaining portion of Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 102 (D.I. 128) as it relates to the relevant Solarcaine® products, and Plaintiffs' Motion for Leave to File a Sur-Reply Brief in Response to Defendants' Reply Brief in Support of Their Motion for Summary Judgment of Invalidity Under 35 U.S.C. §102(b) (D.I. 239).

An appropriate order will be entered.