IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

INTENDIS, INC.	:	
v.	:	Civil Action No. DKC 10-2419
RIVER'S EDGE PHARMACEUTICALS, LLC, et al.	:	

MEMORANDUM OPINION

Presently pending and ready for review in this Lanham Act false advertising case are the motion for a temporary restraining order and preliminary injunction filed by Plaintiff Intendis, Inc. (ECF Nos. 2, 4, and 47), the motion for leave to file a supplemental brief under seal filed by Defendants River's Edge Pharmaceuticals, LLC and Kylemore Pharmaceuticals, LLC (ECF No. 54), the motion in limine to exclude certain categories of evidence filed by Defendants (ECF No. 56), and the motion for leave to file deposition designations of Defendants' Rule 30(b)(6) witness under seal filed by Plaintiff (ECF No. 71). The issues are fully briefed and a hearing was held on October 21 and 29, 2010. The court now rules. For the reasons that follow, Plaintiff's motions for a temporary restraining order and preliminary injunction will be denied and Defendants' motion in limine will be denied. The motions for leave to file under seal will also be denied.

I. Background

A. Factual Background

This case is a dispute between two pharmaceutical companies that distribute and market competing prescription acne medications. Plaintiff Intendis, Inc. ("Intendis") markets the NeoBenz® Wash Plus Pack, a name-brand drug, and Defendants River's Edge Pharmaceuticals, LLC ("River's Edge) and Kylemore Pharmaceuticals, LLC ("Kylemore") market and distribute the BP 7% Wash External Kit ("BP Wash Kit"), a generic drug. Intendis accuses Defendants of making false or misleading statements about the BP wash on the product insert page, the package label, and in marketing information distributed to national pharmacies and pharmacy databases. Intendis filed motions for a temporary restraining order and preliminary injunction and seek an order requiring Defendants to submit supplemental information to the national pharmacy databases to correct or clarify the false or misleading statements made in their prior submissions to these databases and to post statements on their website.

1. The Products

Intendis markets and distributes NeoBenz Wash Plus Pack, a prescription drug package that contains NeoBenz Micro Wash, a 7% benzoyl peroxide wash, and NeoBenz Micro SD, pre-filled sponge applicators with a 5.5% benzoyl peroxide cream. The two

products are designed for use in tandem for the topical treatment of mild to moderate acne vulgaris. According to the product insert included with every package of the NeoBenz Wash Plus Pack, the active ingredient, benzoyl peroxide, is incorporated into patented porous microspheres to "provide gradual release of active ingredient into the skin and absorb natural skin oils." (Pl.'s Hr'g Ex. 2, Intendis Package Insert for NeoBenz). The specific release rate of active ingredient in the NeoBenz wash is not disclosed in the product packaging or marketing materials.

River's Edge markets and distributes the BP Wash Kit, a prescription drug package that contains a 7% benzoyl peroxide wash ("BP wash") and a 5.5% benzoyl peroxide cream ("BP cream").[1] The BP Wash Kit also comes with sponge applicators and is intended as a topical treatment for acne. According to the product insert, the active ingredient in the product, benzoyl peroxide, is "incorporated into a series of microscopic concentric vesicules of oil and water. . . . [that] results in the release of the active ingredient into the skin over a sustained period of time." (Pl.'s Hr'g Ex. 1, River's Edge

[1] Intendis alleges that Kylemore also distributes the BP Wash Kit and is a division, close affiliate, or alter ego of River's Edge. (ECF No. 30 ¶¶ 34-43). No evidence regarding Kylemore was presented at the hearing.

Package Insert for BPO). The BP wash does not use the microsponge delivery system. Instead, it contains the skin conditioner Incroquat OSC, a self-emulsifier and polymeric drug delivery system that incorporates the benzoyl peroxide into vesicules of oil and water.

The BP Wash Kit entered the market in July 2010. Intendis first learned of its introduction when it received an alert from Wolters Kluwer, a national pharmaceutical database that lists drugs and tracks their sales. Wolters Kluwer, like other national pharmacy databases, classifies drugs based on four categories of information: (1) the drug's active ingredient, (2) the route of administration, (3) the strength of the active ingredient, and (4) the dosage of the active ingredient. Using these four items, the databases assign each drug a generic product identifier code ("GPI" or "GCN"). Pharmacies rely on a drug's GPI code to make dispensing decisions and will substitute lower priced generic drugs for name-brand drugs with the same GPI unless otherwise prohibited by state law.

Intendis received an alert in July 2010 because the BP Wash Kit had been given the same GPI code as the NeoBenz Wash Plus Pack. Pharmacies began to substitute the BP Wash Kit for NeoBenz prescriptions because the acquisition price, *i.e.*, the price pharmacies paid for the drug, was significantly lower than

the price for NeoBenz.[2] As a result, NeoBenz sales began to decline.

2. The Alleged False Statements

Intendis alleges that Defendants made false or misleading statements about the BP Wash Kit on the product's label, in its package insert, and in deal sheets about the product that were submitted to national pharmacy chains and pharmacy databases. The allegedly offending statements are that: (1) the BP wash is a 7% benzoyl peroxide wash; (2) the BP Wash Kit provides sustained release of the active ingredient through the use of microscopic vesicules; (3) the BP Wash Kit contains microscopic vesicules; and (4) the BP Wash Kit has a shelf life of twenty-four months.[3] The first three statements are found on the product insert that is included in every package of the kit and was separately submitted to the national pharmacy databases along with the package label and a standard form. The twenty-four-month shelf-life claim was made in the deal sheets that

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[2] In July 2010, the acquisition price for NeoBenz Wash Plus Pack was listed in the Wolters Kluwer database at $122.19 compared to $96.47 for the BP Wash Kit. (Pl.'s Hr'g Ex. 60, at INTENDIS 001334).

[3] Intendis's amended complaint no longer asserts that the statement regarding the sustained release of active ingredient in the BP wash is false. In argument at the hearing, however, counsel for Intendis continued to make the argument that this statement is false or misleading.

River's Edge submitted to national pharmacy chains and pharmacy database organizations to announce the release of the product. (*See* Pl.'s Hr'g Exs. 54-58). None of these documents claim that the BP wash is equivalent to or substitutable for the NeoBenz wash. There is no other evidence that any statements were made by Defendants asserting that the BP Wash Kit was equivalent to and/or a substitute for the NeoBenz Wash Plus Pack.

3. Testing of Drugs

Both parties conducted or commissioned tests of the BP wash products to support their respective claims regarding its strength of active ingredient, its shelf life, the rate of release of the active ingredient, and the presence of microscopic vesicules.

a. Active Ingredient Strength and Shelf Life

In order to test the percentage of active ingredient present in the medications, high performance liquid chromatography analysis ("HPLC") was conducted. HPLC is an analytical separation technique used to quantitate how much of an analyte is in a drug product. In this case, it was used to determine the amount of benzoyl peroxide present in samples of the BP wash and BP cream.[4]

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[4] For gel and lotion formulations of benzoyl peroxide, there is an industry standard monograph that provides parameters

Intendis commissioned Dow Pharmaceutical Sciences ("Dow") to conduct HPLC tests of the BP wash and BP cream. The Dow HPLC tests were conducted on two lots of the BP wash and two lots of the BP cream. Lot 6619 was tested a month after manufacture and determined to have between 88.0% and 90.0% of the claimed BP wash label strength of 7% benzoyl peroxide. Lot 6298 was tested fifteen months after manufacture and had between 80.1% and 80.5% of claimed label strength. For both lots of the BP cream tested, Dow's results showed the percentage benzoyl peroxide to be between 93.8% and 95% of the strength claimed on the label. The margin of error for Dow's test results was plus or minus 2%. (Prelim. Inj. Hr'g Tr. 181, Oct. 21, 2010).

Defendants rely on tests conducted by the product's manufacturer, Sonar Products, Inc. ("Sonar"). Sonar conducts HPLC tests routinely as part of the manufacturing process and for stability reporting. The first three lots of any new product are stability tested as well as the first lot of any subsequent year. In addition, Sonar conducted new tests of the lots that had been tested by Dow for comparison.

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for label strength claims. For gel formulations, a benzoyl peroxide solution must contain between 90% and 110% of the claimed label strength of active ingredient. For lotion, the monograph permits solutions where the benzoyl peroxide is between 90% and 125% of the claimed label strength. For benzoyl peroxide washes and creams, there is no industry standard monograph.

In October 2010, Sonar conducted an HPLC test of Lot 6619 of the wash and the results showed it contained 98.6% of the label strength of benzoyl peroxide. Sonar had previously tested Lot 6619 at the time of its manufacture in July 2010, and at that time it had 101% of label strength. In Sonar's prior tests of Lot 6298 of the BP wash, a sample kept at room temperature had remained at 100% of label strength for twelve months, and a sample subjected to accelerated aging had decreased to 98.6% of label strength after three months. In Sonar's tests of the BP cream, Lot 6495 started at 100% of label strength and remained at 100% after three months of accelerated aging and six months at room temperature. For other lots of the BP wash and BP cream not tested by Dow, Sonar's HPLC results were all close, if not equal, to 100% of label strength and well within the industry standard monographs for gels and lotions.

Dow used the results from its HPLC tests to calculate the shelf life of the BP wash and BP cream based on the rate of degradation of benzoyl peroxide. Dow based its calculations on several assumptions: (1) that the product was manufactured to contain 100% of the label strength of active ingredient, (2) that the active ingredient had a steady rate of degradation, and (3) that the shelf life of the product corresponded to the time when the active ingredient was at 90% or more of the label

strength. With these parameters, Dow calculated that Lot 6619 of the BP wash had a shelf life of less than two months and Lot 6298 of the BP wash had a shelf life of eight months. For the BP creams, Dow calculated that Lot 6513 had a shelf life of nine months and Lot 6495 had a shelf life of eleven months.

b. Release Rates

In order to establish the release rates of the products, both parties conducted Franz Cell tests. The Franz Cell test is used to measure the *in vitro* permeation rate of active ingredients in solution. The test utilizes a Franz Cell apparatus that contains two distinct chambers separated by a membrane designed to represent human skin. The test solution is placed into the top chamber and measurements are taken from the bottom chamber at regular intervals to measure the amount of active ingredient that has diffused through the membrane.

Defendants commissioned Dr. Richard Cummings, Chair of Biochemistry at Emory University School of Medicine, to conduct Franz Cell tests to compare the release rates of BP wash and NeoBenz wash. Dr. Cummings's results showed that, on average, the BP wash released at a rate that was 15% slower than the NeoBenz wash.

Dow also conducted a Franz Cell test to compare the release rates of the two washes. The results of Dow's Franz Cell test

were deemed inadmissible at the hearing because Intendis failed to provide a proper foundation for their authentication and admission. Intendis has proffered that their results showed that the products have different release profiles and that the BP wash had a release rate 50% slower than the NeoBenz rate.

Despite this dispute about the specific release rate for either product, both products release the active ingredient gradually over time.

c. Presence of microscopic vesicules

As part of Dow's testing, Dow was asked to do a microscopy analysis of the BP wash and BP cream to ascertain the presence of microscopic vesicules. To that end, technicians at Dow were asked to photograph the BP wash and BP cream at magnification levels of 400x and 1000x. Intendis attempted to introduce the report and photographs as exhibits during the hearing, but no evidence was presented to confirm the substance of the photographs or to lay a foundation for their admission. Intendis has proffered that the photographs do not reveal the presence of concentric vesicules of oil and water.

Defendants submitted the expert testimony of Dr. Thomas Freund, the lab director and director of scientific affairs at Sonar to refute this opinion. Dr. Freund's view is that the photographs do not prove or disprove the existence of concentric

vesicules. In his opinion, the pictures of the BP cream did show vesicules and the pictures of the BP wash showed what could be remnants of vesicules, but the photos' exposure and lighting conditions rendered them inconclusive. Dr. Freund separately explained that one could infer the existence of concentric vesicules in the BP wash from the fact that it allows for extended release of the active ingredient and the fact that it contains Incroquat OSC.

4. Harm

Intendis has lost sales to Defendants from pharmacies' substitution of the BP Wash Kit for the NeoBenz Wash Plus Pack. Although the exact amount of lost sales has not been provided, Intendis's Head of Sales, Gary Tighe, testified that it could be determined using sales data maintained by Wolters Kluwer or other pharmacy databases. In addition to the Intendis and River's Edge products, there is now a third pharmaceutical company offering a topical acne wash treatment with the same GPI code, Seton. Seton's product is priced lower than the NeoBenz Wash Plus Pack and BP Wash Kit. Seton's introduction into the marketplace makes predictions about the impact of granting an injunction more complicated. If the BP wash is no longer listed in the same GPI code, its lost sales may be transferred to the new Seton product instead of River's Edge, making it difficult

to quantify the loss to BP wash and difficult to determine whether any benefit would inure to Intendis.

B. Procedural History

Intendis filed its initial complaint, along with a motion for a temporary restraining order and preliminary injunction on September 1, 2010. (ECF Nos. 1-4). The complaint alleged that Defendants were disseminating false or misleading statements by proclaiming that the BP wash contained benzoyl peroxide incorporated into microscopic vesicules, resulted in the release of the active ingredient over a sustained period of time, and was equivalent to and/or otherwise substitutable for Intendis's NeoBenz Wash Plus Pack. (ECF No. 1). Defendants River's Edge and Kylemore filed their opposition to the motion for a temporary restraining order and preliminary injunction on September 8, 2010. (ECF No. 21). Shortly thereafter, counsel for Defendants filed a motion to withdraw because of a potential conflict arising from their firm's representation of affiliates of Intendis's parent corporation, Bayer AG. (ECF No. 31). Defendant's motion to withdraw was denied without prejudice at a hearing on September 30, 2010. (ECF No. 36). In the interim, Intendis had filed an amended complaint that withdrew its request for a temporary restraining order and shifted the focus of its allegations. (ECF No. 30). In the amended complaint,

Intendis added the allegation that BP wash does not contain benzoyl peroxide at a concentration of 7% with a shelf life of twenty-four months and omitted the statement alleging that the BP wash did not provide sustained release of the active ingredient over time. (*Id.* ¶ 2). Defendants submitted their answer to the amended complaint on October 12, 2010. (ECF No. 45). At the court's request, Intendis submitted an amended motion for preliminary injunction to correspond with the amended complaint on October 13, 2010. (ECF No. 47). Prior to the hearing, Defendants submitted their opposition to the amended motion for preliminary injunction (ECF No. 51) and a motion in limine to preclude Intendis from offering expert testimony on certain topics and to exclude an FDA warning letter sent to River's Edge. (ECF No. 56).

A hearing on Intendis's motion for preliminary injunction took place on October 21 and 29, 2010. Intendis presented testimony from the following witnesses: Gary Tighe, Intendis's Head of Sales; Dr. Simon Yeh, Assistant Director of the Analytical Sciences Department at Dow, Expert in Analytical Chemistry; Dr. James Del Rosso, Dermatologist, Expert in Dermatology; Dr. Elena Serbinova, Intendis's Director of Regulatory Affairs and Compliance; and Brendan Murphy, President of River's Edge.

At the conclusion of Intendis's evidence, Defendants moved pursuant to Fed.R.Civ.P. 52(c) for a judgment on partial findings denying Intendis's request for preliminary injunction. Defendants' motion was denied (ECF No. 72), and they proceeded to present additional evidence. Defendants presented testimony from the following witnesses: Brendan Murphy, President of River's Edge; Dr. Thomas Freund, Sonar's Director of Scientific Affairs, Expert in High Performance Liquid Chromatography (by video deposition); Dr. Richard Cummings, Chair of Biochemistry at Emory University School of Medicine, Expert in Biochemistry and Molecular Structure; and Gary Tighe, Intendis's Head of Sales (by video deposition). In rebuttal, Intendis called Dr. Gareth Winckle from Dow as an Expert in Pharmaceutical Sciences.

II. Motion in Limine and Other Evidentiary Issues

Prior to the evidentiary hearing, Defendants filed a motion in limine seeking to preclude Intendis from introducing testimony from Doctors Del Rosso and Yeh at the hearing and an FDA warning letter as an exhibit. (ECF No. 56). At the beginning of the hearing on October 21, 2010, the court explained that rather than ruling on the motion in limine at the start, evidentiary issues would be taken up as they arose throughout the proceedings. Where appropriate, objections to the introduction of evidence were sustained, but Doctors Del

Rosso and Yeh were not precluded from testifying entirely. To the extent Defendants raised questions regarding their qualifications or relevant knowledge, appropriate weight was given to the credibility and relevance of their opinions when assessing the facts. With respect to the FDA warning letter, Intendis was permitted to introduce it as Plaintiff's Exhibit 4, (*See* ECF No. 73), but it has not affected the court's ruling. To the extent it was not explicit at the hearing, Defendants' motion in limine will be denied.

III. Preliminary Injunction

A. Standard of Review

Intendis has moved for a preliminary injunction pursuant to Federal Rule of Civil Procedure 65 and the Lanham Act. (ECF No. 47). Under Fed.R.Civ.P. 65, the decision whether to issue a preliminary injunction is committed to the sound discretion of the trial court. "A preliminary injunction is an extraordinary remedy." *Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 345 (4th Cir. 2009), *vacated on other grounds by* 130 S.Ct. 2371 (2010) *and reissued in part*, 607 F.3d 355 (4th Cir. 2010). To obtain a preliminary injunction, a plaintiff must establish four elements: "[1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of

equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* at 364 (quoting *Winter v. Natural Res. Def. Council, Inc.*, 129 S.Ct. 365, 374 (2008)). All four requirements must be satisfied. *Id.*

B. Analysis

Intendis argues that it has demonstrated a likely violation of the Lanham Act and the court should issue a preliminary injunction requiring Defendants to halt, alter, or correct their promotional statements. (ECF No. 48, at 3). Intendis further contends that it has shown it is likely to suffer irreparable harm absent preliminary relief, that the balance of equities tip in its favor, and that an injunction would be in the public interest. Defendants counter that Intendis has failed to make its case for any of the requirements to obtain preliminary injunctive relief.

1. Likelihood of Success

Intendis's amended complaint asserts one count of deceptive advertising and unfair trade in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Intendis asserts that Defendants have made false statements or omissions of fact, including establishment and "tests prove" claims in violation of the Lanham Act.

Section 43(a) of the Lanham Act provides the following:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which-
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> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
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> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
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> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a).

A plaintiff asserting a false advertising claim under the Lanham Act must establish that:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another’s product;
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> (2) the misrepresentation is material, in that it is likely to influence the purchasing decision;
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> (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience;

> (4) the defendant placed the false or misleading statement in interstate commerce; and
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> (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002) (citing *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 310-11 (1st Cir. 2002), *cert denied*, 537 U.S. 1001 (2002)).

For liability to arise under the false advertising provisions of the Lanham Act, "the contested statement or representation must be either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context." *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir. 1997) (internal quotation marks omitted). Depending on the nature of the alleged false statements, different standards of proof apply. "Where the advertisement is literally false, a violation may be established without evidence of consumer deception." *Scotts Co.*, 315 F.3d at 273. "But if 'a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead

or confuse consumers.'" *Id*. (quoting *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2d Cir. 1992)). For example, in *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 906 F.Supp.178 (S.D.N.Y. 1995), the defendants included a bar chart in advertisements showing that doctors had prescribed the drug Tagamet 200 million times more than Pepcid. However, in small print at the bottom, the ad revealed that Tagamet had been prescribed since 1977 whereas Pepcid had only been prescribed since 1986. The court held that while the statement in the bar chart was literally true, it conveyed or implied a meaning that was false—that doctors had prescribed Tagamet over Pepcid in a head-to-head battle. *Id.* at 186.

Establishment or "tests prove" claims are a subset of false advertising claims where the alleged false or misleading statements either explicitly or implicitly indicate that there is test data in support of the claims made. In these situations, a plaintiff need only show either (i) that the tests were not sufficiently reliable to permit the conclusion for which they are cited, or (ii) that the tests, even if reliable, do not establish the proposition asserted by the defendant. *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992); *see also McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*,

938 F.2d 1544, 1549 (2d Cir. 1991). If the Defendants' statements are classified as "tests prove" or "establishment claims," then Intendis does not have to prove that they are actually false, only that Defendants' tests did not support the conclusions Defendants have made about the product at issue. *See Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1310 (11th Cir. 2010). The statement need not explicitly reference tests in order be classified as an establishment claim. It is sufficient if the statement(s) "necessarily implied that it was validated by some clinical test." *C.B. Fleet Co.*, 131 F.3d at 436.

Intendis asserts that it has a likelihood of success for four independent reasons: (1) Defendants have made statements regarding the BP Wash Kit that are literally false; (2) Defendants' package contains establishment claims that imply that Defendants have reliable tests to support the statements, but for which Defendants have not conducted tests; (3) Defendants deliberately made false statements with the intent and effect of causing pharmacies to treat its BP wash as a substitute for NeoBenz, and (4) Defendants made a false claim that BP wash could be substituted for NeoBenz. (ECF No. 48, at 5-10). The evidence does not support Intendis's claims.[5]

[5] In their opposition to Intendis's initial motion for temporary restraining order and preliminary injunction,

Intendis alleges that four statements made by Defendants in the package inserts or promotional materials are literally false: (1) that the BP wash is a 7% benzoyl peroxide wash; (2) that the BP Wash Kit provides sustained release of the active ingredient through the use of microscopic vesicules; (3) that the BP Wash Kit contains microscopic vesicules; and (4) that the BP Wash Kit has a shelf life of twenty-four months. Beginning with the first statement, Intendis has only identified one lot of the BP Wash Kit with less than 90% of the claimed label strength when considering the margin of error of Dow's test. The other lot tested by Intendis and those tested by Defendants all had at least 90% of the claimed label strength of benzoyl peroxide. Based on this evidence, the court is not prepared to say that Intendis is likely to prove that the claimed label

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Defendants argued that the statements made in the product insert do not constitute "advertising" or "promotion" as referenced in the Lanham Act and on that basis all of Intendis's arguments failed. (ECF No. 21, at 10-13). Defendants pointed to a number of cases holding that product inserts do not constitute advertising, including a prior opinion from this court holding that "point-of-purchase materials that merely restate the language approved for the label cannot fairly be characterized as advertising." *Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 549 F.Supp.2d 708, 717 (D.Md. 2008) Subsequent evidence, however, made explicit that the product inserts were submitted to the national pharmaceutical databases, along with datasheets, as a way to advertise the BP Wash Kit, and Defendants did not pursue this argument at the hearing.

strength is false; to the contrary, the evidence to date supports the veracity of Defendants' claimed label strength.

The next two statements can be considered together. There is no real dispute that the BP wash provided sustained release; Intendis challenges only the rate of release and whether it is accomplished with the use of the microscopic vesicules. Defendants make no claim to a specific rate of release or that the BP wash has an identical rate of release to the NeoBenz wash. As a result, the second identified statement is not literally false. With respect to the presence of vesicules, Plaintiff's primary evidence that the statement is false is photographs alleged to show few or no vesicules in samples of the BP wash. These photographs were deemed inadmissible, but even if they had been admitted, they would not prove Intendis's point. The lighting and exposure in the photographs makes it difficult to discern their contents, but they do appear to contain at least some vesicules. In addition, Defendants have further refuted Intendis's argument with the testimony of Dr. Freund who stated that one could infer that the BP wash has microscopic vesicules because it uses Incroquat OSC as an emulsifier and from the simple fact that the product has delayed release.

The final alleged literal falsehood is the claim that the BP wash has a twenty-four-month shelf life. Intendis disputes the accuracy of this claim and offers as evidence extrapolations of the data from its HPLC testing done on several samples of the BP wash and BP cream demonstrating that samples of the BP wash it tested had shelf lives of two and eight months and the BP cream samples had shelf lives of nine and eleven months. Defendants counter with testimony from Dr. Freund that Sonar follows the USP guidelines for testing product stability and that Sonar's benzoyl peroxide products do not show significant degradation for two years. (Prelim. Inj. Hr'g Tr. 150-57, Oct. 29, 2010). Dr. Freund also testified about Sonar's stability test results conducted on samples of the BP wash after twelve months where the product continued to show 100% of label strength and a sample of the BP cream after eighteen months that tested at 100% of label strength. (*Id.* at 182-84).

Dow's methodology is unreliable because it was based on very limited data and incorporated assumptions that were unsubstantiated. In contrast, the FDA's preferred methodology involves a trend analysis where one takes data over a period of time, takes the log of that activity, and then extrapolates over a two-year time period. The data from the manufacturer, Sonar, showing a twenty-four-month shelf life is entitled to more

weight given that it incorporates data over a long term and was ascertained using an FDA-approved method. Thus, the evidence presented on this issue to date supports the veracity of Defendants' claimed shelf life and there is little support for Intendis's assertion that the claim is false.

In addition to its claims that Defendants have made literally false statements, Intendis argues that Defendants have failed to produce test results to substantiate the claims about the BP Wash Kit made on the product insert and in promotional materials. Intendis argues that the facts of this case align with those of *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 590 (3d Cir. 2002), where the United States Court of Appeals for the Third Circuit deemed "Mylanta Night Time Strength" a false statement because the manufacturers came forward with no evidence to show that their product was specifically formulated for night time relief or was more effective than other products at providing night time relief for heartburn. Intendis argues that, as in *Novartis*, Defendants had a burden to provide evidence of tests or analyses to confirm its claimed label strength and shelf life and they have failed to meet that burden. (ECF No. 48, at 8-9).

Defendants argue that the statements made on the product label and product insert do not refer to tests or imply that

tests were conducted. (ECF No. 51, at 19). Defendants argue that where the advertisement does not contain an express assertion or language implying that a test was conducted, the establishment claim standard of proof does not apply. *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 436 (4th Cir. 1997). In addition, Defendants also argue that, to the extent statements made about BP wash imply that tests were conducted, the reference is only meaningful if a single test can prove whether the statement is true. (ECF No. 51, at 19). Defendants argue that if it is not clear what tests were done or what tests could be done to validate the statements, the advertisements are not making an establishment claim. (*Id.*).

Intendis's establishment claim theory suffers from two general flaws. First, although not always explicit in the case law, this theory is typically argued or applied where comparative statements have been made indicating one product's superiority or specific suitability for a given purpose. *See e.g., C.B. Fleet Co.*, 131 F.3d at 433, 435-36 (considering whether establishment claim analysis applied to advertisement stating "Massengill cleanses better than Summer's Eve"); *Osmose*, 612 F.3d at 1310 (affirming district court's classification of statements referring to findings about the safety and efficacy

of a competing category of products as "tests prove" or "establishment" claims); *Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc.*, 299 F.3d 1242, 1248 (11th Cir. 2002) ("As the common law of false advertising has developed, several circuits have determined that the nature of a plaintiff's burden in proving an advertisement to be literally false should depend on whether the defendant's advertisement cites consumer testing. . . . If an advertisement cites such testing, the advertisement is labeled as an 'establishment' claim.") (citing *C.B. Fleet Co.*, 131 F.3d at 435); *EFCO Corp. v. Symons Corp.*, 219 F.3d 734, 739-40 (8th Cir. 2000) (noting that test prove claims fall under the umbrella of comparative advertising); *Castrol, Inc.*, 977 F.2d at 59, 63 (applying establishment claim analysis to advertisement stating "tests prove Quaker State 10W-30 protects better than any other leading 10W-30 motor oil"); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1546 (2d Cir. 1991) (upholding district court's factual determination that defendant had produced inadequate test results to back up advertisements' claims that "in doctor supervised clinical studies . . . [AF] Excedrin was shown to provide greater headache relief" and "AF Excedrin 'works better' than ES Tylenol"); *Proctor & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 115, 119 (2d Cir. 1984) (applying establishment claim

analysis to statements such as "dermatologists proved it in clinical tests, New Wondra improves the condition of rough dry skin better" and "it relieves dry skin better than any leading lotion"); *see also Rhone-Poulenc Rorer Pharm., Inc. v. Marion Merrell Dow, Inc.,* 93 F.3d 511, 514-15 (8th Cir. 1996). The establishment claim or tests prove cases do not stand for the proposition that a defendant must provide reliable test data for every factual statement in an advertisement to defend against allegations of false advertising. Here, there are no alleged statements from Defendants that explicitly reference testing or make claims of comparative superiority. Intendis did not specifically identify the statements that it contends imply the existence of supporting test data other than to refer generally in the complaint to "statements about function, contents, and other measurable qualities of the BP[] Wash" (ECF No. 48, at 8) (citing ECF No. 1 ¶¶ 47-48). On these facts, the establishment or tests prove claim analysis is not applicable.

The second general flaw is that the establishment claim analysis fails on its merits. Defendants have produced documents from the manufacturer of the BP Wash Kit providing confirmation of the products' percentage of active ingredient and shelf life. The mere fact that Intendis conducted similar

tests and reached different results is not sufficient to challenge the methodology and results provided by Defendants.

There is a similar lack of evidence for Intendis's final two theories: (1) that Defendants deliberately made false statements with the intent and effect of causing pharmacies to treat its BP wash as a substitute for NeoBenz, and (2) that Defendants made a false claim that BP wash could be substituted for NeoBenz. Intendis has no evidence that Defendants have ever claimed that BP wash is a substitute for NeoBenz. While a representative of River's Edge testified that its goal in creating the BP wash was to create a product that was as close as possible to the NeoBenz wash, (Prelim. Inj. Hr'g Tr. 13-14, Oct. 29, 2010), as discussed above, it does not appear that any of the statements on the package insert or promotional materials are false. Moreover, the data sheets sent to national buyers and retail chains include the disclaimer that "River's Edge does not claim bioequivalence of its product(s) to other brand(s) unless explicitly noted," (ECF No. 51, at 11) (citing Ex. D-53), and Intendis's Head of Sales admitted that the pharmacy databases do not list the products as equivalents (*Id.* at 12) (citing Tighe Dep. at 125-26). It is not actionable to seek to obtain market share by manufacturing a comparable product that costs less if no false statements are made.

One additional theory was fully explicated by Intendis at the preliminary injunction hearing. At that time, Intendis's counsel argued that Defendants were telling half-truths and omitting key information that was the equivalent of a false statement. When pressed, Intendis's counsel identified the half-truth as the statement on the package insert that the BP Wash Kit product "provided continuous release through the delivery system of vesicules of oil and water." Counsel then backtracked and agreed that Intendis's argument was that the claim of vesicules was literally false and the implied falsehood was the implication that scientific data backed up all of Defendants' claims. (Prelim. Inj. Hr'g Tr. 274-84, Oct. 29, 2010). Without a consistent and coherent explanation of the contours of Intendis's argument, it would indeed be difficult to find that it has an ultimate likelihood of success.

Overall, Intendis has failed to produce evidence to establish with the requisite level of certainty that Defendants made false or misleading descriptions of fact or representations of fact in a commercial advertisement.

2. Irreparable Harm

Intendis argues that because River's Edge is a direct competitor, any false advertising by River's Edge is likely to cause irreparable harm. (ECF 48, at 11). Intendis relies on

case law holding that where a plaintiff shows a likelihood of literal falsity, the court may presume the existence of irreparable harm. (*Id.* at 12) (citing *JTH Tax, Inc. v. H&R Block E. Tax Servs., Inc.*, 128 F.Supp.2d 926, 947-48 (E.D.Va. 2001), *vacated in part on other grounds*, 28 F.App'x. 207 (4th Cir. 2002) and *Schick Mfg., Inc. v. Gillete Co.*, 372 F.Supp.2d 273, 287 (D.Conn. 2005)). These cases predate the more recent Supreme Court opinion in *Winter*, however, which emphasized that parties seeking preliminary injunctions must show that irreparable harm is "likely in the absence of an injunction" and not merely possible, as some courts had been applying the standard. 129 S.Ct. at 375; *see also Salinger v. Colting*, 607 F.3d 68, 78 (2d Cir. 2010) (abandoning presumption of irreparable harm when considering preliminary injunctions in the context of copyright infringement).

Defendants argue that Intendis has not established irreparable harm and that because sales of pharmaceuticals are carefully tracked it would be easy to calculate the extent of Intendis's monetary damages. (ECF No. 21, at 23). In addition, Defendants argue that because Intendis's Head of Sales has admitted that another lower cost competitor, Seton, has entered the market, this competitor would likely obtain any sales that Defendants would lose if an injunction is in place and

Intendis's market position would not change. (ECF No. 52, at 3-4).

In any event, Intendis cannot rely on the presumption of irreparable harm cases of literal falsity because it has not established that the statements were literally false. Nor has Intendis produced separate evidence of irreparable harm. Intendis's Head of Sales testified that it would be possible to determine the sales that Intendis lost to River's Edge and the profits on those lost sales from the information maintained by the national pharmacy databases. (Prelim. Inj. Hr'g Tr. 44, Oct. 21, 2010). Generally, "irreparable injury is suffered when monetary damages are difficult to ascertain or are inadequate." *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994). That does not appear to be case here because any sales Intendis has lost or will lose to River's Edge can be calculated accurately. Intendis did not submit evidence of any less tangible forms of harm, and indeed, Intendis's Head of Sales testified that he did not believe Intendis's reputation was or would be harmed if pharmacists gave consumers the River's Edge product instead of NeoBenz. (Prelim. Inj. Hr'g Tr. 231, Oct. 29, 2010).

3. Balance of Equities

Intendis argues that the balance of equities tips in its favor because Defendants cannot have a legitimate interest in continuing to disseminate false and misleading statements about the BP Wash Kit. (ECF No. 48, at 12). Defendants counter that Intendis has applied the wrong test and argue that the proper way to assess potential harm to Defendants is to calculate the harm that would result from an improperly granted injunction. *See, e.g., Scotts Co.*, 315 F.3d at 284 ("If self-made harm is given substantially less weight . . . then the balance of the harms will almost always favor the plaintiff."). Defendants argue that an injunction of BP wash sales would be particularly detrimental because most pharmacies carry only one or two versions of a product and, thus, anyone who buys from a third party while BP wash is enjoined, such as the new market entrant Seton, is likely to continue buying from that third party even if BP wash is later available. (ECF No. 21, at 24-25). Additionally, Defendants argue that a loss of market share is harder to calculate and to compensate for with monetary damages than a loss of sales. (Id.).

The balance of equities does not favor Intendis at this juncture. Intendis has not established the falsity of

Defendants' claims, and there is no public interest in censoring true statements.

4. Public Interest

Intendis argues that the public interest is served "by ensuring that consumers are not deceived by products they purchase." (ECF No. 48, at 12). Defendants counter that the public also has an interest in free and vigorous competition that leads to lower price alternatives. (ECF No. 21, at 26). Both positions are theoretically defensible, but because Intendis has provided no strong evidence of deception, its argument is not persuasive. Preliminary injunctions are an extraordinary remedy and in the absence of strong evidentiary support the public interest is better served by maintaining the status quo.

IV. Motions to Seal

There are two pending motions to seal: one from Defendants regarding their supplemental brief in opposition to Intendis's amended motion for preliminary injunction along with the accompanying exhibits (ECF No. 54), and one from Intendis regarding deposition designations from Defendants' Rule 30(b)(6) witness, Brendan Murphy (ECF No. 71). A motion to seal must comply with Local Rule 105.11, which provides:

> Any motion seeking the sealing of pleadings, motions, exhibits or other papers to be

> filed in the Court record shall include (a) proposed reasons supported by specific factual representations to justify the sealing and (b) an explanation why alternatives to sealing would not provide sufficient protections. The Court will not rule upon the motion until at least 14 days after it is entered on the public docket to permit the filing of objections by interested parties. Materials that are the subject of the motion shall remain temporarily sealed pending a ruling by the Court. If the motion is denied, the party making the filing will be given an opportunity to withdraw the materials.

This rule endeavors to protect the common law right to inspect and copy judicial records and documents, *Nixon v. Warner Commc'ns, Inc.*, 435 U.S. 589, 597 (1978), while recognizing that competing interests sometimes outweigh the public's right of access, *In re Knight Publ'g Co.*, 743 F.2d 231, 235 (4th Cir. 1984).

Before sealing any documents, the court must provide the non-moving party with notice of the request to seal and an opportunity to object. *Id.* This notice requirement may be satisfied by either notifying the persons present in the courtroom or by docketing the motion "reasonably in advance of deciding the issue." *Id.* at 234. Finally, the court should consider less drastic alternatives to sealing, such as filing redacted versions of the documents. If the court decides that sealing is appropriate, it should also provide reasons,

supported by specific factual findings, for its decision to seal and for rejecting alternatives. *Id.* at 235.

Defendants' motion to seal argues that their supplemental memorandum and the accompanying exhibits, including deposition transcripts from Dr. Freund, Brendan Murphy, Dr. Del Rosso, Dr. Elena Serbinova, and Gary Tighe, as well as other documents exchanged during discovery contain factual information designated as "confidential" or "highly confidential-attorneys' eyes only" pursuant to the parties' stipulated protective order. (ECF No. 54, at 1). Intendis argues with respect to its motion to seal that the deposition designations at issue were designated as attorneys' eyes only by Defendants. Intendis states that it believes the designation is improper and overbroad, but that it was filing under seal given the expedited schedule and out of an abundance of caution. (ECF No. 71, at 1-2).

The parties' motions to seal do not offer either a proposed reason supported by specific factual representations to justify the sealing or an explanation as to why alternatives to sealing, such as redaction, would not provide sufficient protections. The court will deny the motions because they do not comply with Rule 105.11. The parties will have fifteen days to renew their motions with memoranda that comply with Rule 105.11. In the

meantime, the papers will remain temporarily under seal. If the parties do not renew their motions, the papers will be unsealed.

V. Conclusion

For the foregoing reasons, Defendants' motion in limine will be denied, Plaintiff's motions for a temporary restraining order and preliminary injunction will be denied, and both parties' motions to seal will be denied.

/s/
DEBORAH K. CHASANOW
United States District Judge