

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

DESTON THERAPEUTICS LLC and  
UNIGEN PHARMACEUTICALS INC.,

Plaintiffs,

v.

TRIGEN LABORATORIES INC. and  
IRISYS INC.,

Defendants.

HON. JEROME B. SIMANDLE

Civil No. 09-809 (JBS/KW)

**OPINION**

APPEARANCES:

Rodger Dallery Smith, II, Esq.  
Katharyn A. Grant, Esq.  
Saul H. Perloff, Esq.  
MORRIS, NICHOLS, ARSHT & TUNNELL  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899

Counsel for Plaintiffs Deston Therapeutics LLC and Unigen  
Pharmaceuticals Inc.

John C. Phillips, Jr., Esq.  
Brian E. Farnan, Esq.  
Steven M. War, Esq.  
PHILLIPS, GOLDMAN & SPENCE, P.A.  
1200 North Broom Street  
Wilmington, DE 19806

Counsel for Defendants Trigen Laboratories Inc. and Irisys  
Inc.

**SIMANDLE**, District Judge:<sup>1</sup>

This matter is before the Court on a motion to dismiss  
submitted by Defendants Trigen Laboratories Inc. and Irisys Inc.

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<sup>1</sup> The undersigned, a United States District Judge for the  
District of New Jersey, is sitting by designation in the United  
States District Court for the District of Delaware due to a  
vacant judgeship.

[Docket Item 11].<sup>2</sup> Defendants ask the Court to dismiss this patent infringement action brought by Plaintiffs Deston Therapeutics LLC and Unigen Pharmaceuticals Inc., because Plaintiffs' patent claims cannot be construed to include Defendants' product. Plaintiffs' remaining causes of action, Defendants argue, are insufficiently pled. As will be explained at greater length below, the Court finds that patent claim construction would be premature and that Plaintiffs have adequately alleged violations of Section 43(a) of the Lanham Act and the Delaware Deceptive Trade Practices Act, as well as common law unfair competition. The Court will consequently deny Defendants' motion to dismiss.

## **I. FACTUAL ALLEGATIONS**

### **A. Allegations in the Complaint**

The present action turns on Defendants' use (or failure to use) a chemical composition called "u-polycosanol 410" in their purportedly generic version of Plaintiffs' ear drops. While polycosanol (also know as "policosanol") is a general term for a type of alcohol extracted from waxes, Plaintiffs allege that u-polycosanol 410 is a unique polycosanol composition subject to two patents (United States Patent No. 7,034,060 and No. 6,683,116) owned by Plaintiff Unigen. (Compl. ¶¶ 9-13.) The "u"

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<sup>2</sup> Also pending is a joint motion for extension of time for Plaintiffs to oppose Defendants' motion [Docket Item 15]. The Court will grant the parties' request, nunc pro tunc.

is a reference to Unigen and the "410" refers to the product's molecular weight. (Id. at 4 n.2.) The u-polycosanol patents include both "a novel policosanol composition and a method of making the composition from wax secreted by the insect Ericerus pela, a soft scale insect indigenous to southern China." (Id. ¶ 11.) Plaintiff Deston markets Auralgan, a prescription ear drop solution, for which it holds an exclusive license to use Unigen's u-polycosanol 410. (Id. ¶¶ 3, 18-19.)

In July 2009, Defendants began marketing and manufacturing Treagan, an ear drop solution whose packet insert indicates that it contains "u-polycosanol 410 (synthetic)." (Id. ¶¶ 22-23.) Plaintiffs allege that Defendants list u-polycosanol 410 on Treagan's label as a way of insuring that the product will be used by drug wholesalers, distributors, and pharmacies, as a generic equivalent of Auralgan. (Id. ¶¶ 24-29.) To be considered a generic equivalent, a drug must be both pharmaceutically equivalent (the same active ingredients, strength, and dosage form) and bio-equivalent (delivers the active ingredients to the site of action in the body at the same rate and in the same amount). (Id. ¶ 25.) Without both types of equivalence, pharmacists will not substitute a generic drug for a brand-name drug prescribed by a doctor. (Id. ¶ 26.) Drug wholesalers, distributors, pharmacies and pharmacists rely on drug information databases, including First DataBank, to

determine whether a particular drug is truly a generic equivalent of a brand-name product. (Id. ¶ 27.) Defendants, by labeling Treagan to include u-polycosanol 410, have succeeded in having drug information databases, including First DataBank and Medi-Span, link Treagan to Auralgan as a generic equivalent. (Id. ¶¶ 29-30.) Similar ear drops that list polycosanol as an ingredient but not u-polycosanol 410 have not been linked to Auralgan, because of the unique composition of u-polycosanol 410. (Id. ¶ 28.)

As a result of this link between Treagan and Auralgan, sales of Auralgan have eroded as many drug wholesalers, distributors, pharmacies and pharmacists across the country purchase Treagan as a substitute for Auralgan. (Id. ¶ 30.) Defendants do not have a license to manufacture or use u-polycosanol 410 under either of Unigen's patents. (Id. ¶ 31.) Plaintiffs allege that if Treagan truly contains Plaintiffs' novel chemical composition in u-polycosanol 410 then Defendants are infringing on Plaintiffs' patents and if Treagan does not contain Plaintiffs' u-polycosanol 410 then its advertisements and promotional claims regarding Treagan's equivalence to Auralgan are false. (Id. ¶¶ 32, 44.) Plaintiffs' complaint alleges that Defendants are infringing on Plaintiffs' patents (Count One), or in the alternative that Defendants have engaged in false advertising (Count Two) and unfair competition (Count Three) in violation of Section 43(a) of

the Lanham Act, that they have violated the Delaware Deceptive Trade Practices Act (Count Four) and engaged in unfair competition prohibited by common law (Count Five).

## **B. The Patents**

Attached to Plaintiffs' complaint are the two United States Patents Nos. 6,683,116 (" '116 Patent") and 7,034,060 (" '060 Patent"). (Compl. Exhs. A & B.) Both patents are entitled "Polycosanols from Ericerus Pela Wax" and in both patents the specifications state, "As used herein the term 'polycosanols' refers to the mixture of higher primary aliphatic alcohols derived from the hydrolysis of the wax of the Ericerus pela." (Compl. Exh. A at 8; Compl. Exh. B. at 8.) The specifications also state, "It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention as claimed." (Compl. Exh. A at 7; Compl. Exh. B. at 8.)

The '116 Patent includes forty-seven claims, including six independent claims. (Compl. Exh. A at 17-20.) The first five claims read as follows:

What is claimed is:

1. A polycosanols composition of matter comprised of 35% to 55% of long chain aliphatic alcohols, wherein said alcohols are selected from the group consisting of 1-hexacosanol (~20%-30%), 1-octacosanol (~15%-25%), 1-triacontanol (~2%-4%), and 1-tetraconsanol (~1%-3%).

2. The composition of claim **1**, wherein said

composition is derived from the wax of the insect Ericerus pela.

3. A polycosanol composition of matter comprised of 75%-100% of long chain aliphatic alcohols, wherein said alcohols are selected from the group consisting of 1-hexacosanol (~30%-50%), 1-octacosanol (~25%-45%), 1-triacontanol (~4%-10%), and 1-tetraconsanol (~3%-9%).

4. The composition of claim **3**, wherein said composition is derived from the wax of the insect Ericerus pela.

5. A composition of higher primary aliphatic alcohols having from 24 to 30 carbon atoms (C24-30) from the wax of the insect Ericerus pela prepared according to a method comprising the steps of . . . [steps omitted].

(Id. at 17.)

The '060 Patent included five claims, with one independent claim. (Compl. Exh. B. at 19-20.) The first three claims read:

The invention claimed is:

1. A polycosanol composition of matter comprised of long chain aliphatic alcohols 1-hexacosanol (~20%-50%), 1-octacosanol (~15%-45%), 1-triacontanol (~2%-10%), and 1-tetraconsanol (~1%-9%).

2. The composition of claim **1**, wherein said composition is derived from the wax of the insect Ericerus pela.

3. The composition of claim **1**, wherein said long chain aliphatic alcohols comprise 35%-100% of said composition.

(Id.)

### **C. Defendants' Motion**

Defendants attack both prongs of Plaintiffs' alternative pleadings. They maintain that because their u-polycosanol 410 is synthetic, it cannot possibly infringe upon Plaintiffs' patents. According to Defendants, Plaintiffs' patents only cover

polycosanol compositions derived from the Ericerus pela insect. Defendants argue that Plaintiffs' false advertising and unfair competition claims fail because, inter alia, Plaintiffs have not sufficiently alleged that the u-polycosanol 410 in Treagan is not equivalent to the u-polycosanol 410 in Auralgan, nor have Plaintiffs adequately alleged that Treagan's label constitutes commercial advertising or promotion under the Landham Act. The Court will address these arguments below.

## **II. DISCUSSION**

### **A. Standard of Review**

On a motion to dismiss pursuant to Rule 12(b)(6), the Court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008) (quoting Pinker v. Roche Holdings Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002)). Thus, "to survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, --- U.S. ---, 129 S. Ct. 1937, 1949 (2009); Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009).

## B. Patent Infringement

The sole basis of Defendants' attack on Plaintiffs' infringement action is Defendants' proposed construction of the patent claims to exclude any polycosanol not derived from the wax of the Ericerus pela. Plaintiffs respond that claim construction is premature and that the question of whether or not Defendants derived their u-polycosanol 410 from Ericerus pela is one of fact not to be decided on this motion to dismiss. The Court agrees with Plaintiffs that claim construction is premature and will decline to dismiss the patent infringement claim at this stage.

To resolve an allegation of patent infringement, "The court must first interpret the claim and determine the scope and the meaning of the asserted patent claims, and then compare the properly construed claims to the allegedly infringing device." Liquid Dynamics Corp. v. Vaughan Co., 355 F.3d 1361, 1367 (Fed. Cir. 2004). While it is true that claim construction is a matter of law to be determined by the Court, the process for properly construing a patent claim is unsuited for a motion to dismiss. In the seminal case Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), the Federal Circuit described the claim construction process:

"To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991); accord Autogiro Co. of Am. v. United States, 181 Ct. Cl. 55, 384 F.2d 391, 396-98, 155 U.S.P.Q. (BNA) 697,



701-03 (Ct. Cl. 1967). "Expert testimony, including evidence of how those skilled in the art would interpret the claims, may also be used." Fonar Corp. v. Johnson & Johnson, 821 F.2d 627, 631 (Fed. Cir. 1987).

Id. at 979. "The court may, in its discretion, receive extrinsic evidence in order 'to aid the court in coming to a correct conclusion' as to the 'true meaning of the language employed' in the patent." Id. at 980; see Gemtron Corp. v. Saint-Gobain Corp., 572 F.3d 1371, 1377 (Fed. Cir. 2009) ("The court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources 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.") (internal punctuation and citation omitted).

As a consequence, many courts in this circuit and elsewhere have declined to construe patent claims on a motion to dismiss. See, e.g., In re Bill of Lading Transmission & Processing Sys. Patent Litig., No. 09-2050, 2010 U.S. Dist. LEXIS 16110, at \*12 (S.D. Ohio Feb. 23, 2010); Yangaroo Inc. v. Destiny Media Techs., No. 09-462, 2009 U.S. Dist. LEXIS 82052, at \*7-8 (E.D. Wis. Aug. 31, 2009); Bird Barrier Am., Inc. v. Bird-B-Gone, Inc., No. 09-0418, 2009 U.S. Dist. LEXIS 125475, 7-8 (C.D. Cal. Mar. 1, 2009); Tech. Patents, LLC v. Deutsche Telekom AG, 573 F. Supp. 2d 903,

920 (D. Md. 2008); Cima Labs, Inc. v. Actavis Group HF, No. 06-1999, 2007 U.S. Dist. LEXIS 41516, at \*8-9 (D.N.J. June 7, 2007); Schreiber v. Eli Lilly & Co., No. 05-2616, 2006 U.S. Dist. LEXIS 13477, at \*17 (E.D. Pa. Mar. 27, 2006). Defendants attempt to distinguish these cases on the grounds that many involved efforts to introduce extrinsic evidence on a Rule 12(b)(6) motion, noting that here no party has offered extrinsic evidence nor documentation of prosecution history. This only serves to illustrate the point. The fact that the parties in this case have obeyed the procedural rules constraining Rule 12(b)(6) motions does not mean that the record is sufficiently complete to warrant construing the patent claim contrary to Plaintiffs' allegations of infringement. The Court will follow this lengthy line of cases and conclude that claim construction is not appropriate upon the present record of this Rule 12(b)(6) motion.

Claim construction is generally performed through the claim construction process leading to and including the Markman hearing. For example, in the District of New Jersey's Local Patent Rules,<sup>3</sup> that court, for the purposes of patent case management, has provided for early disclosures of the parties' contentions of infringement and non-infringement, together with the exchange of relevant documents; the parties are called upon

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<sup>3</sup> See N.J. L. Pat. R., Part IV, reproduced in N.J. L. Civ. R. 9.3.

to exchange proposed terms for claim construction, followed by the exchange of preliminary claim construction and extrinsic evidence, and then their joint claim construction and prehearing statement including a summary of construction experts' reports, preparatory to the Markman hearing,<sup>4</sup> following procedures similar to the local patent rules of each court that has adopted patents rules to date.<sup>5</sup> The submissions to the judge for the claim construction hearing are similarly spelled out and apply to all Markman hearings, being designed to promote both early and reliable claim constructions by the court.<sup>6</sup> These Markman processes recognize that typically, as in the present case, the complaint and the patents' language are necessary but insufficient components of the record for claim construction.<sup>7</sup>

The Court can perhaps envision a patent infringement cause

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<sup>4</sup> See N.J. L. Pat. R. 4.1-4.3.

<sup>5</sup> N.D. Cal. Patent L.R. 4; S.D. Cal. Patent L.R. 4; N.D. Tex. Miscellaneous Order No. 62 ¶ 4; E.D. Tex. P.R. 4; D. Minn. L.R. Form 4; W.D. Pa. L.P.R. 4; N.D. Ga. Patent L.R. 6. These claim construction practices derive from the seminal case of Markman v. Westview Instruments, 517 U.S. 370 (1966).

<sup>6</sup> See, e.g., N.J. L. Pat. R. 4.5.

<sup>7</sup> It may be prudent, to enhance efficiency of litigation, for the parties to agree upon the few key terms that need to be construed on an expedited basis, saving others for the Court's attention, if necessary, at a later date before trial. See Peter S. Menell, et al., Patent Case Management Judicial Guide (Federal Judicial Center 2009) at § 5.2.3.1.3. This topic may be addressed in the initial scheduling conference to be convened shortly in this case, with an eye toward streamlining the claim construction process.

of action for which patent claims could be construed on a motion to dismiss, but this is not such a case. While it is true that both the '116 Patent and the '060 Patent place a great deal of emphasis on polycosanol derived from the Ericerus pela insect, the claim language -- "always . . . the appropriate starting point," Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362, 1366 (Fed. Cir. 2000) (internal punctuation and citation omitted) -- draws a distinction between several unique polycosanol compositions and those compositions when derived from Ericerus pela wax. In both the '116 Patent and the '060 Patent, the first claim for coverage details a chemical composition and the second claim seeks coverage of the described composition when extracted from the insect. (Compl. Exh. A at 17; Compl. Exh. B. at 19.) If the first two claims necessarily were limited to polycosanol from Ericerus pela, then the subsequent claims would be entirely duplicative. "Under the doctrine of claim differentiation, two claims of a patent are presumptively of different scope." Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1366-1367 (Fed. Cir. 2000). Defendants are correct that this presumption is not irrebuttable, but in order to determine whether it has been rebutted the Court must have a complete record. See Kraft Foods, 203 F.3d at 1368 ("Notwithstanding Kraft's contentions, we agree with the district court that the written description and prosecution history

overcome any presumption arising from the doctrine of claim differentiation . . ."); Multiform Desiccants, Inc. v. Medzam Ltd., 133 F.3d 1473, 1479-80 (Fed. Cir. 1998) ("[T]he doctrine of claim differentiation can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence."); Tandon Corp. v. United States Int'l Trade Com., 831 F.2d 1017, 1023-1024 (Fed. Cir. 1987) (finding the presumption overcome by the specification and the prosecution history). Moreover, though the specifications include a definition of "polycosanol" limited to the Ericerus pela variety, the specifications also make clear that they are "not restrictive of the invention as claimed." (Compl. Exh. A at 7; Compl. Exh. B. at 8.) Claim construction in this case is more complicated than Defendants allow and should not be determined at this stage.

Furthermore, contrary to Defendants' suggestion, Plaintiffs do not concede in their complaint either that the patent only covers polycosanol derived from Ericerus pela or that Defendants' u-polycosanol 410 is synthetic and therefore not derived from the insect. The complaint may plausibly be read as distinguishing between patent coverage for a novel polycosanol composition and coverage for a method of making the composition from the insect. It states: "In 2002, Unigen's Chief Scientific Officer invented a novel policosanol composition and a method of making the

composition from the wax secreted by the insect Ericerus pela, a soft scale insect indigenous to southern China. In 2003, Plaintiff applied for patents on this policosanol composition, its method of manufacture, and its use in the treatment of certain medical conditions.” (Compl. ¶ 10.) Thus, under Plaintiffs’ complaint, and without yet having the benefit of a record sufficient for claim construction under Markman, it is a plausible reading of the complaint that the patents cover both a particular chemical composition and a method of making the composition, but the covered composition need not necessarily be created by the method involving the insect.

Similarly, Plaintiffs do not concede that Defendants’ u-polycosanol 410 is in fact synthetic. Instead, Plaintiffs merely quote the labeling on Treagan’s packaging. (Compl. ¶¶ 23, 40.) Nowhere do Plaintiffs allege that Treagan does not use u-polycosanol derived from the Ericerus pela.

In light of the jurisprudence holding that claim construction is generally not appropriate on a motion to dismiss, the ambiguity and possible conflict between the plain language of the patent claims and the specifications, and the fact that Plaintiffs have not resolved these issues in their complaint, the Court will decline to engage in patent claim construction or find as a matter of law that Defendants’ u-polycosanol 410 cannot infringe on Plaintiffs’ patents because it is not derived from

Ericerus pela. The Court will deny Defendants' motion to dismiss Plaintiffs' patent infringement cause of action.

**C. False Advertising Under the Lanham Act**

Defendants move to dismiss Plaintiffs' false advertising claim under the Lanham Act on the grounds that Plaintiffs have not adequately alleged that Defendants made a false statement, that the statement actually misled customers, or that Defendants engaged in commercial advertising or promotion. For the reasons expressed below, the Court finds that Plaintiffs have adequately alleged their false advertising claim under the Lanham Act.

False advertising is prohibited under Section 43(a)(1)(B) of the Lanham Act, which reads in relevant part:

(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 --

. . .

(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, 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)(1)(B). To establish a Lanham Act claim based on false or misleading representations in commercial advertising or promotion a plaintiff must allege "1) that the defendant has

made false or misleading statements as to his own product or another's; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc." Warner-Lambert Co. v. BreathAsure, Inc., 204 F.3d 87, 91-92 (3d Cir. 2000).

Defendants begin their attack with the first prong of the false advertising claim, arguing that Plaintiffs must allege some specific difference between Plaintiffs' u-polycosanol 410 and Defendants' u-polycosanol 410 in order to sufficiently allege that Defendants have made a false statement by listing u-polycosanol 410 among the ingredients in Treagan. Defendants appear to misunderstand the nature of Plaintiffs' alternative pleading. Under Rule 8(d)(2) (until 2007, Rule 8(e)(2)), Fed. R. Civ. P., Plaintiffs were permitted to "set out 2 or more statements of a claim or defense alternatively or hypothetically." Moreover, "If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient." Id.; see Indep. Enters. v. Pittsburgh Water & Sewer Auth., 103 F.3d 1165, 1175-76 (3d Cir. 1997) ("This Rule permits inconsistency in both legal and factual allegations . . .").



Plaintiffs have alleged that either Defendants' u-polycosanol 410 contains the same chemical composition as Plaintiffs' u-polycosanol 410 so that Defendants are infringing Plaintiffs' patents or Defendants' u-polycosanol 410 is not the same chemical composition as Plaintiffs' u-polycosanol 410 so that Treagan is not pharmaceutically equivalent to Auralgan and by using the term "u-polycosanol 410" in the list of ingredients Defendants are falsely stating that equivalence. (Compl. ¶ 44.) As discussed above, Plaintiffs have adequately alleged that Defendants' u-polycosanol 410, synthetic or otherwise, infringes on Plaintiffs' patents protecting novel polycosanol compositions. This allegation is therefore sufficient to support the alternative allegation that if Defendants' u-polycosanol 410 does not infringe (meaning it is not the same as Plaintiffs' u-polycosanol 410) then Defendants have made a false statement by listing that ingredient on Treagan and presenting Treagan as a true equivalent to Auralgan. See Fed. R. Civ. P. 8(d)(2) ("If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient."). It is not necessary for Plaintiffs to know the precise chemical composition of Treagan at this stage. See 4 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure, § 1282 ("Those who drafted Rule 8(e)(2) [now Rule 8(d)(2)] sought to free federal procedure from this insistence on certainty in the pleadings.")

The Court recognizes that Defendants vehemently deny the first premise. Defendants argue that they may manufacture and use u-polycosanol 410 so long as it is not derived from Ericerus pela. If that turns out to be true, then it may also be true that Defendants may market a u-polycosanol 410 that is chemically identical to Plaintiffs' u-polycosanol 410 without either infringing on Plaintiffs' patents or making any false representations regarding the equivalence of Treagan and Auralgan. The Court, however, must accept Plaintiffs' allegations as true at this stage and has declined to adopt Defendants' construction of the patent claims at issue for the purposes of this motion to dismiss. Plaintiffs have therefore sufficiently alleged, in the alternative, that Defendants made a false or misleading statement.

Plaintiffs have also sufficiently alleged "facts suggesting that the marketplace was actually confused or misled, not just that the marketplace could have been confused or misled." See Accenture Global Servs. GMBH v. Guidewire Software, Inc., 581 F. Supp. 2d 654, 667 (D. Del. 2008). As alleged, drug information databases have listed Treagan as a generic equivalent of Auralgan because of the listed ingredient "u-polycosanol 410(synthetic)," and so drug wholesalers, distributors, pharmacies and pharmacists have been misled to purchase Treagan as pharmaceutically equivalent to Auralgan, when it is not. (Compl. ¶¶ 24-30.)

These allegations are sufficient to show that customers were actually misled. Moreover, if the Court finds that Treagan's statements are "literally false," because Treagan does not actually contain u-polycosanol 410, then the Court "may grant relief without considering whether the buying public was actually misled." Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 586 (3d Cir. 2002). Plaintiffs have sufficiently alleged material deception as well as literal falsity.

Finally, Plaintiffs have sufficiently alleged that Treagan's label and product insert constitute "commercial advertising or promotion" under the Lanham Act. Defendants argue that in order to fall under Section 43(a)(1)(B) of the Lanham Act as "commercial advertising or promotion" Plaintiffs must allege that the label and insert "propose a commercial transaction," quoting Accenture, 581 F. Supp. at 667, and also must allege "widespread dissemination [of the advertisements] within the relevant industry," quoting Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc., 314 F.3d 48, 57 (2d Cir. 2002). The Third Circuit has not directly addressed the meaning of "commercial advertising or promotion," but it has found a product's name and label to be false advertising. Novartis Consumer Health, 290 F.3d at 585, 599-600; see Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990) (recognizing a line of

cases that "emphasize that an advertising claim is not shielded from the Lanham Act merely by appearing only on a product's label"). "Advertising is not limited to newspaper, television or radio announcements; any notice addressed to the public serves the same purpose." Warren Corp. v. Goldwert Textile Sales, Inc., 581 F. Supp. 897, 900 (S.D.N.Y. 1984).

Plaintiffs have alleged that drug wholesalers, distributors, pharmacies, and pharmacists are purchasing Treagan precisely because of the contents of its label (and the presence of the ingredient "u-polycosanol 410"). In the generic pharmaceuticals market, Plaintiffs allege, listed ingredients are the principal form of advertising. Drugs that proclaim, via their labels and product inserts, to include the same active ingredients as a brand-name drug will be purchased instead of that brand-name drug. According to Plaintiffs, this is what happened with Treagan. Moreover, Plaintiffs have alleged that the information on Treagan's label has been broadcast via drug information databases so that purchasers "across the country" have been misled to believe that Treagan is a substitute for Auralgan. (Compl. ¶ 30.) Assuming that widespread dissemination is required to constitute commercial advertising or promotion, Plaintiffs have sufficiently alleged such dissemination of commercial advertising.

In sum, the Court rejects Defendants' arguments and finds

that Plaintiffs have adequately alleged that Defendants engaged in commercial advertising or promotion through which they made false statements that have actually misled consumers. The Court will deny Defendants' motion to dismiss Plaintiffs' false advertising claim under the Lanham Act.<sup>8</sup>

**D. Unfair Competition Under the Lanham Act**

Defendants attack Plaintiffs' allegations of unfair competition under Section 43(a)(1)(A) of the Lanham Act on largely the same grounds as Defendants sought dismissal of the false advertising claim.<sup>9</sup> Namely, Defendants maintain that Plaintiffs have not adequately alleged the falsity of Defendants'

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<sup>8</sup> Though not raised in this motion, the Court finds that Plaintiffs have sufficiently alleged that Treagan has moved through interstate commerce and that Plaintiffs have suffered some injury due to Plaintiffs' false advertising, thereby satisfying the fourth and fifth elements of a Lanham Act false advertising claim. See Warner-Lambert, 204 F.3d at 91-92.

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To state a claim pursuant to 15 U.S.C. § 1125(a) of the Lanham Act, a plaintiff must allege: (1) that the defendant uses a false designation of origin; (2) that such use of a false designation of origin occurs in interstate commerce in connection with goods or services; (3) that such false designation is likely to cause confusion, mistake or deception as to the origin, sponsorship or approval of the plaintiff's goods and services by another person; and (4) that the plaintiff has been or is likely to be damaged.

Parker v. Google, 242 F. App'x 833, 838 (3d Cir. 2007) (citing AT & T Co. v. Winback & Conserve Program, Inc., 42 F.3d 1421, 1428 (3d Cir. 1994)).

representation that Treagan is equivalent to Auralgan or any actual confusion. As discussed at length in Part II.C, supra, the Court has found that Plaintiffs have adequately alleged that Defendants have made false representations regarding the ingredients of Treagan and its equivalence to Auralgan. In that same discussion the Court further found that Plaintiffs have sufficiently alleged that consumers have actually been misled or confused by this claim of equivalence.<sup>10</sup> The Court will consequently deny Defendants' motion to dismiss Plaintiffs' unfair competition claims under the Lanham Act.

#### **E. Delaware Deceptive Trade Practices Act**

Defendants raise no new arguments in requesting dismissal of the Deceptive Trade Practices Act ("DTPA"), 6 Del. C. § 2532. Instead, Defendants note that the same standard that governs claims under Section 43(a) of the Lanham Act and also governs claims under the DTPA. See Schering-Plough Healthcare Prods. v. Neutrogena Corp., No. 09-268, 2010 U.S. Dist. LEXIS 24511, at \*10-11 (D. Del. Mar. 15, 2010) ("... proof of a Lanham Act

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<sup>10</sup> Plaintiffs' Lanham Act claims are premised on the allegation that Treagan does not contain the true chemical equivalent of Plaintiffs' u-polycosanol 410. Therefore, contrary to Defendants' suggestion, the indication on Treagan's label that Defendants' u-polycosanol 410 is "synthetic" does not resolve any confusion, because it does not distinguish the chemical makeup of the two substances (as opposed to the source). Whether Defendants' u-polycosanol is synthetic or not goes to Defendants' arguments regarding Plaintiffs' patents and whether those patents cover polycosanol compositions not derived from the Ericerus pela, not Plaintiffs' alternative claims under the Lanham Act.

claim would necessarily meet the requirements for a claim under the DTPA.”); Monsanto Co. v. Syngenta Seeds, Inc., 443 F. Supp. 2d 648, 653 (D. Del. 2006); Toro Co. v. Textron, Inc., 499 F.Supp. 241, 249 n.17 (D. Del. 1980). Therefore, Defendants assert that because Plaintiffs’ Lanham Act claims fail, so too should their DTPA claims fail. The Court has found that Plaintiffs have adequately alleged violations of Section 43(a) of the Lanham Act and consequently will deny Defendants’ motion to dismiss Plaintiffs’ DTPA claim.<sup>11</sup>

#### **F. Common Law Unfair Competition**

Defendants argue that Plaintiffs have not stated a claim for common law unfair competition because they have not alleged a reasonable probability of a business expectancy or any misconduct on the part of Defendants to interfere with such an expectancy. Though “notoriously undefined,” this district has recently adopted the definition of unfair competition from the Delaware Superior Court, which stated that the “elements of the tort of unfair competition are that the plaintiff has a reasonable expectancy of entering a valid business relationship, with which the defendant wrongfully interferes, and thereby defeats the plaintiff's legitimate expectancy and causes him harm.”

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<sup>11</sup> The Court rejects Defendants’ argument that Plaintiffs have not specified the provisions of the DTPA on which they base their claims. Plaintiffs have cited six sections of the DTPA, providing Defendants sufficient notice of the provisions they intend to rely upon.

Ethypharm S.A. v. Abbott Labs., 598 F. Supp. 2d 611, 618 (D. Del. 2009) (quoting Total Care Physicians, P.A. v. O'Hara, 798 A.2d 1043, 1057 (Del. Super. Ct. 2001)). The Court finds that Plaintiffs have alleged a business expectancy by asserting that Auralgan "has become a leading prescription product for the treatment of otic [ear] disorders," (Compl. ¶ 20), but that as a result of Defendants' false marketing of Treagan as a generic equivalent, sales of Auralgan have "eroded," (Compl. ¶ 30). Thus, Defendants' misconduct has allegedly interfered with expected sales. Plaintiffs have stated a claim for unfair competition under Delaware law.

### **III. CONCLUSION**

For the foregoing reasons, the Court will deny Defendants' motion to dismiss. The accompanying Order shall be entered.

**July 12, 2010**  
Date

**s/ Jerome B. Simandle**  
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JEROME B. SIMANDLE  
United States District Judge