

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CONCORDIA PHARMACEUTICALS, INC.,)	
)	Civil Action No. 3:14CV00016
Plaintiff,)	
)	<u>MEMORANDUM OPINION</u>
v.)	
)	Hon. Glen E. Conrad
METHOD PHARMACEUTICALS, LLC, et al.,)	Chief United States District Judge
)	
Defendants.)	

In the instant action, Concordia Pharmaceuticals, Inc. (“Concordia”) asserts claims under the Lanham Act and Virginia law against Method Pharmaceuticals, Inc. and Matthew Scott Tucker (collectively, “Method”). Concordia has moved for summary judgment on three of its claims, and Method has moved for summary judgment as to all claims. The court held a hearing on the motions on March 3, 2016.¹ For the following reasons, Concordia’s motion will be denied and Method’s motion will be granted in part and denied in part.

Summary of the Facts

I. Plaintiff Concordia and the Donnatal® Product Line

Concordia is an international company incorporated under the laws of Barbados, which markets, sells, and distributes pharmaceutical products. On March 20, 2014, Concordia announced that it had entered into an agreement to acquire the Donnatal® line of products (“Donnatal”) from former plaintiff PBM Pharmaceuticals, Inc. (“PBM”). Concordia completed the acquisition in May of 2014.

¹ During the March 3, 2016 hearing, the court also heard oral argument on the parties’ motions to exclude expert witnesses. Those motions will be addressed in a separate memorandum opinion.

Donnatal is a line of combination phenobarbital and belladonna alkaloid (“PBA”) products that is used as adjunctive therapy in the treatment of irritable bowel syndrome and acute enterocolitis. Donnatal is available in two formulations: immediate-release tablets and fast-acting elixir.² The tablets and elixir are available by prescription only.

Donnatal products have a unique regulatory history and status. Donnatal was first introduced in the 1930s by A.H. Robins Company. In 1962, Congress amended the Federal Food, Drug, and Cosmetic Act (“FDCA”) to require drug manufacturers to prove that new drugs are safe and effective for their labeled indications in order to obtain approval by the Food and Drug Administration (“FDA”). The amendment also required the FDA to conduct a retrospective evaluation of drugs that had previously been approved under the FDCA between its enactment in 1938 and 1962. Donnatal was one of more than 3,400 drugs affected by the amendment.

In the 1970s, the FDA began a process of evaluating the safety and efficacy of PBA products under the Drug Efficacy Study Implementation (“DESI”) review program. On June 20, 1978, the FDA required any drugs that were involved in the review process to obtain an approved New Drug Application (“NDA”) or Abbreviated New Drug Application (“ANDA”) to remain on the market. On December 30, 1980, A.H. Robins, PBM’s predecessor-in-interest, obtained conditional approval ANDAs for its Donnatal tablets and elixir. Drugs manufactured under such a conditionally approved ANDA can be legally marketed until the FDA resolves questions regarding the drugs’ effectiveness under the FDCA. At this time, although the FDA has concluded that the Donnatal products are safe, it has yet to determine their effectiveness.

² Another formulation, Donnatal Extentabs, was discontinued by PBM and is not being marketed by Concordia.

For over thirty years, Donnatal faced competition from generic PBA products that were pharmaceutically equivalent to Donnatal. Beginning in August of 2011, manufacturers of the generic versions began to take their products off the market.³ Once the inventories of previously manufactured generic products were eliminated, Donnatal was the only line of PBA products available for prescription.

In order to enter the PBA product market, Concordia purchased the rights to make and sell Donnatal from PBM. Concordia completed the acquisition of the Donnatal product line on May 15, 2014. The Asset Purchase Agreement between PBM and Concordia transferred a variety of assets, including the conditionally-approved ANDAs for Donnatal.

II. Defendant Method and its Efforts to Develop and Market Me-PB-Hyos

Defendant Method is a wholesale drug distribution company based in Arlington, Texas. The company was founded by Defendant Tucker in November of 2012. Tucker is also the company's president. Prior to starting Method, Tucker worked for a company that manufactured a product called Re-PB-Hyos, which contained the same active ingredients as Donnatal.

In the summer of 2013, Method decided to look for a contract manufacturer for a new product that would be pharmaceutically equivalent to Donnatal. The new product was eventually named Me-PB-Hyos. Method contacted Winder Laboratories, LLC ("Winder"), a Georgia company that had previously developed another product for Method. In December of 2013, Method issued four purchase orders to Winder for the development of Me-PB-Hyos, including a purchase order for stability tests. Around the same time, Winder and Method discussed

³ The parties dispute why this occurred. Concordia maintains that the manufacturers of generic versions of Donnatal products either voluntarily withdrew or were forced off the market by the FDA, while Method contends that PBM forced its competitors off the market. Ultimately, this dispute is not material to the disposition of the parties' motions.

manufacturing an initial order for three commercial batches of the product. Winder and Method also agreed on the price that Winder would charge for supplying Me-PB-Hyos.

In March of 2014, Method used publicly-available copies of the Donnatal product labels and package inserts as templates for its Me-PB-Hyos labels and inserts. Tucker forwarded copies of the Donnatal labels to Platinum Press, a healthcare packaging company, and asked that the company change the name of the product to Me-PB-Hyos and the name of the distributor to Method Pharmaceuticals, LLC. After making a series of additional revisions requested by Tucker, Platinum Press sent Tucker proofs of the requested Me-PB-Hyos labels on March 24, 2014.

Method subsequently listed the Me-PB-Hyos products with two pharmaceutical industry databases, Medi-Span and First Databank (collectively, the “databases”). According to the plaintiff’s evidence, the databases are used nationwide by market participants throughout the pharmaceutical industry, including drug manufacturers, wholesalers, third-party payors, pharmacies, and pharmacists, to evaluate medications that are currently available on the market or will soon be available. The databases are also used to determine whether generic substitutes are available for brand name products.

On March 31, 2014, Chris Boone, Method’s vice president of operations, forwarded the Me-PB-Hyos label proofs prepared by Platinum Press, along with new product submission forms, to Medi-Span. On or about April 1, 2014, Method’s Me-PB-Hyos products were listed in the Medi-Span database. Based on the information provided by Method, the Me-PB-Hyos products were assigned the same Generic Product Identifier (“GPI”) as Donnatal. The marketing start date

for the Me-PB-Hyos products was listed as June 1, 2014, and the marketing category was listed as “unapproved drug other.” Defs.’ Statement of Undisputed Material Facts (“SUMF”) Ex. K.

On April 14, 2014, PBM, Concordia’s predecessor-in-interest, contacted Medi-Span and advised that “Medi-Span’s published listings of Me-PB-Hyos Oral Elixir and Me-PB-Hyos Oral Tablets are inaccurate, could cause harm to patients, and could expose [Medi-Span] to legal liability for damages.” Defs.’ SUMF Ex. J. PBM requested that Medi-Span delist the Me-PB-Hyos products immediately.

That same day, a representative of Medi-Span contacted Boone and inquired as to whether “both Me-PB-Hyos products are available for patient use at this time.” Pl.’s SUMF Ex. 5. In response, Boone advised the Medi-Span representative that the products were “not currently available,” and that Method hoped to have more information the following week as to when it would begin shipping the products. Pl.’s SUMF Ex. 6.

In addition to Medi-Span, Method sought to have its Me-PB-Hyos products listed in First Databank’s pharmaceutical database. However, First Databank refused to list the Me-PB-Hyos products without validation from DailyMed, a website operated by the National Library of Medicine, which provides information regarding marketed drugs in the United States, including FDA label information and package inserts. Consequently, Method sent the Me-PB-Hyos tablet and elixir labels to Intagras, a company that provided DailyMed listing services to Method, and advised the company that it needed to “move forward with listing these products with [the] FDA and DailyMed.” Pl.’s SUMF Ex. 36.

On May 27, 2014, Intagras advised Method that it would need additional information regarding the Me-PB-Hyos products, including the marketing category, the marketing start date, a

description of the tablet, and the name of the manufacturer. In response, Tucker sent Intagras an email listing the marketing category for the products as “unapproved drug/other”; the marketing start date as “06/01/2014”; and the manufacturer as “Winder Labs.” Pl.’s SUMF Ex. 18.

The Me-PB-Hyos products were subsequently listed with DailyMed. Consistent with the information provided by Method, the DailyMed listings for the Me-PB-Hyos tablets and elixir listed a “marketing start date” of “06/01/2014” and a “marketing category” of “unapproved drug other.” Pl.’s SUMF Exs. 45 & 46. The indications and usage section of the Daily-Med listings for the Me-PB-Hyos products provided as follows:

Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the following indications as “possibly” effective: For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. May also be useful as adjunctive therapy in the treatment of duodenal ulcer

Id. The same information was contained in the product inserts for the Me-PB-Hyos products.

On June 3, 2014, Method resubmitted the Me-PB-Hyos product labels to First Databank. Method’s submission listed a “planned launch date” of June 1, 2014. Pl.’s SUMF Ex. 15. Method’s submission was processed by First Databank, and the Me-PB-Hyos products were listed in the First Databank pharmaceutical database in early June 2014.

In addition to the product labels and inserts, Method provided pricing information for the Me-PB-Hyos products to Medi-Span and First Databank. The listed prices for the Me-PB-Hyos products were lower than the listed prices for the related Donnatal products. Method indicated that the pricing information was effective as of April 1, 2014.

On September 15, 2014, after the instant action was filed, Tucker emailed Winder to express “concerns” regarding the “PB-Hyos Project.” Pl.’s SUMF Ex. 21. The email provided, in pertinent part, as follows:

The litigation on this project has been going on since May and we have incurred substantial legal fees. We just entered a second round of discovery from the courts. I know that Winder hasn’t started anything on this project at this time and we are discussing internally about the viability of the project for the long run. We think it might be best to bail on this project at Winder and not bring Winder into the litigation. With that, we know there is raw material at your facility and development fees that have been paid. Since nothing has been done to date, we would like to credit the development fees against the IDA project and I will ask Anthony to have the raw material returned.

Id.

That same day, in response to an inquiry from Medi-Span regarding the status of Me-PB-Hyos, Boone advised Medi-Span that “Me-PB-Hyos is an active product and will be available to ship by 11/15/14.” Pl.’s SUMF Ex. 7. Boone also indicated that “[t]he pricing and label on file are current and correct.” Pl.’s SUMF Ex. 7. In response to a follow-up email requesting clarification of what Boone meant by “available to ship by 11/15/14,” Boone replied as follows:

The products were never launched. Within days of our listing with Medi-Span back in April, Method was sued by a competitor, PBM Pharmaceuticals. PBM sought a preliminary injunction to prevent Method’s launch. The court did not grant PBM’s request, but did order expedited discovery, including a deposition of a Medi-Span representative. The parties were just again before the court in the case, which is still pending. Based on the status of the case, Method intends to launch in mid-November.

Id. In reply, Medi-Span requested that Method resubmit the National Drug Code (“NDC”) number for Me-PB-Hyos when Method launched the products.

Ultimately, Method never launched the Me-PB-Hyos products, and the products were not manufactured by Winder or any other company. In mid-October 2014, Medi-Span removed the listings for the Me-PB-Hyos products. Around the same time, First Databank moved its listings for the Me-PB-Hyos products from active listings to archived listings.

III. The Effects of the Listings

After Method's Me-PB-Hyos products were listed with Medi-Span and First Databank, Me-PB-Hyos was linked to Donnatal as an available product in the dispensing software utilized by Rite-Aid. Additionally, information obtained from Symphony Health Solution's industry database (the "Symphony data") reveals that by the week ending June 13, 2014, pharmacists had begun submitting claims for Me-PB-Hyos. The Symphony data also reveals instances in which insurance coverage for Donnatal was refused following the listing of Me-PB-Hyos. On at least one occasion, a claim for Donnatal was refused while a subsequent claim for Me-PB-Hyos was approved. However, because Me-PB-Hyos was unavailable at the time, the patient was switched to different medications altogether and did not receive a prescription for Donnatal.

According to Concordia's evidence, third-party payors began placing Me-PB-Hyos on their formularies as a generic alternative to Donnatal. In at least one case, Donnatal was actually removed from a formulary with Me-PB-Hyos listed as the preferred generic alternative.

Concordia has also proffered evidence indicating that some doctors stopped prescribing Donnatal altogether based on the mistaken belief that it was no longer available. For instance, one prescriber, Colleen Nakumura, testified that "12 or 14 prescriptions . . . were turned down" in June of 2014, and that she "slowly stopped writing [prescriptions] because [she] didn't want to get

the phone calls back” from pharmacies indicating that Donnatal was not available. Pl.’s SUMF Ex. 87 at 26; Defs.’ Mem. in Opp’n to Pl.’s Mot. for Summ. J. Ex. R at 22.

The Symphony data proffered by Concordia indicates that the total number of prescribers who wrote prescriptions for Donnatal decreased by nearly eighteen percent in the twelve-month period following Method’s claimed launch date. Likewise, weekly prescription counts for Donnatal decreased after the listings for Me-PB-Hyos were posted on the prescription drug databases. The parties dispute, however, whether the decline in the number of prescribers and prescription counts was caused by the listings for Method’s Me-PB-Hyos products.

Concordia sells Donnatal to third-party wholesalers and repackagers. From January 2012 to June 2014, the prices of Donnatal products increased by 1,480%. On June 11, 2014, after acquiring the rights to Donnatal from PBM, Concordia increased the prices again by 100%. It is undisputed that Concordia’s profits and profit margin for Donnatal tablets and elixir increased after Method’s Me-PB-Hyos products were listed with the databases. However, Concordia claims that its profits would have been even higher if Method had not listed the Me-PB-Hyos products, and, thus, that it experienced lost profits as a result of the listings.

Procedural History

PBM commenced this action against defendant Method on April 29, 2014, asserting claims of false advertising and unfair competition under the Lanham Act and related claims under state law. On June 2, 2014, PBM filed an amended complaint that added Concordia as a plaintiff. The plaintiffs then amended their complaint to name as additional defendants Tucker, Winder, and Steven Pressman, the managing member of Winder.

The plaintiffs filed a third amended complaint on February 10, 2015, which constitutes the operative complaint in the case. The third amended complaint asserts the following claims under federal and state law: (I) false advertising in violation of § 43(a) of the Lanham Act; (II) unfair competition in violation of § 43(a) of the Lanham Act; (III) violation of the Virginia Consumer Protection Act; (IV) civil conspiracy in violation of Virginia common law; (V) violation of the Virginia Business Conspiracy Act; (VI) unjust enrichment under Virginia common law; and (VII) tortious interference with contract or business expectancy in violation of Virginia common law.

Method filed an answer to the third amended complaint on February 27, 2015. Tucker filed his answer on April 2, 2015. On July 1, 2015, Winder and Pressman were dismissed from the case for lack of personal jurisdiction. On July 2, 2015, PBM was dismissed from the case upon the joint request of the parties. Accordingly, Concordia is the sole remaining plaintiff, and Method and Tucker are the sole remaining defendants.

Following the completion of discovery, the parties filed cross-motions for summary judgment. The motions have been fully briefed and are ripe for review.

Standard of Review

An award of summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). In determining whether a genuine dispute of material fact exists, the court must “view the facts and all justifiable inferences arising therefrom in the light most favorable to the nonmoving party.” Libertarian Party of Va. v. Judd, 718 F.3d 308, 313 (4th Cir. 2013). “When faced with cross-motions for summary judgment, [courts] consider each motion separately on its own merits to determine whether either of the parties deserves judgment as a matter of law.”

Bacon v. City of Richmond, 475 F.3d 633, 636-37 (4th Cir. 2007). “The court must deny both motions if it finds that there is a genuine dispute of material fact, but if there is no genuine issue and one or the other party is entitled to prevail as a matter of law, the court will render judgment.” Sky Angel U.S., LLC v. Discovery Commc’ns., LLC, 95 F. Supp. 3d 860, 869 (D. Md. 2015) (internal citation and quotation marks omitted).

Discussion

Concordia has moved for summary judgment on its claims for false advertising, unjust enrichment, and tortious interference. Method has moved for summary judgment as to all claims. The court will address each claim in turn.

I. False Advertising under the Lanham Act

In Count I of the third amended complaint, Concordia asserts a claim for false advertising under the Lanham Act. Section 43(a)(1)(B) of the Lanham Act prohibits an individual or entity from making a “false or misleading description of fact, or false or misleading representation of fact, which . . . 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.” 15 U.S.C. § 1125(a)(1)(B). Thus, a plaintiff asserting a claim for false advertising under this statute 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; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (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 (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) (quoting Cashmere &

Camel Hair Mfrs. Inst. v. Saks Fifth Ave., 284 F.3d 302, 310-11 (1st Cir. 2002)); see also PBM Prods., LLC v. Mead Johnson & Co., 639 F.3d 111, 120 (4th Cir. 2011).

A. False Statement in a Commercial Advertisement

The first element of a claim for false advertising under § 43(a) of the Lanham Act requires a plaintiff to demonstrate that the defendant made a false statement in a commercial advertisement about its own products or another's products. Scotts Co., 315 F.3d at 272; see also C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P., 131 F.3d 430, 434 (4th Cir. 1997) ("Under [§ 43(a) of the Lanham Act], both false advertising of a competitor's products and false advertising of one's own products are actionable."). For either type of advertisement to constitute a violation of § 43(a), "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., 131 F.3d at 434 (internal citation and quotation marks omitted). "Where the advertisement is literally false, a violation may be established without evidence of consumer deception." PBM Prods., 638 F.3d at 120 (internal citation and quotation marks omitted). However, "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.

In moving for summary judgment on Concordia's false advertising claim, Method argues that it made no false or misleading statements regarding the Me-PB-Hyos products. In response to Method's motion, and in support of its own motion for summary judgment, Concordia argues that the product labels, inserts, and database listings for the Me-PB-Hyos products contained literally false statements regarding product availability, FDA approval, pharmaceutical

equivalence, and price. In reply, Method maintains that the allegations of literal falsity are unsupported by the record.⁴

“In analyzing whether an advertisement is literally false, . . . a court must determine, first, the unambiguous claims made by the advertisement . . . , and second, whether those claims are false.” Scotts Co., 315 F.3d at 274. “A literally false message may either be explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.” Id. Ultimately, “[w]hether an advertisement is literally false is an issue of fact.” C.B. Fleet Co., 131 F.3d at 434.

1. Availability of Me-PB-Hyos

Concordia first claims that Method made literally false statements regarding the availability of the Me-PB-Hyos products. Concordia emphasizes that Method identified a planned launch date of June 1, 2014 in its submissions to First Databank, and that it likewise listed a marketing start date of June 1, 2014 in its submissions to the FDA. Concordia notes that the June 1, 2014 marketing start date was then imported into the Medi-Span listings for Me-PB-Hyos tablets and elixir. During his deposition, Tucker described the June 1, 2014 date as the “date [Method] anticipated having the product ready to be able to market . . . [or] sell.” Pl.’s SUMF Ex. 84 at 116. Concordia emphasizes, however, that no Me-PB-Hyos products were ever

⁴ At this stage of the proceedings, Method does not dispute that product labels and inserts provided to a pharmaceutical database can constitute commercial advertising for purposes of the Lanham Act. See, e.g., Sandoz Pharms. Corp. v. Richardson-Vicks, Inc., 902 F.3d 222, 231 (3d Cir. 1990) (citing cases that support the proposition that “an advertising claim is not shielded from the Lanham Act merely by appearing only on a product’s label”); Merck Eprova AG v. BrookStone Pharms., LLC, 920 F. Supp. 2d 404, 424 (S.D.N.Y. 2013) (holding that labels and package inserts distributed to pharmaceutical databases “constitute advertising under the Lanham Act”). Instead, Method argues that it made no literally false statements at the time it supplied the labels, inserts, and other product information to the databases.

manufactured and, thus, that products could not have been available for prescription as of June 1, 2014.

In response, Method argues that Concordia is unable to point to a single instance in which Method claimed that its products would be commercially available as of a particular date, and that Concordia improperly equates the date on which a product will be marketed with that on which the product will be commercially available to the public. Method notes that within two weeks of its products being listed with Medi-Span, Method advised Medi-Span that its Me-PB-Hyos products were not yet available. Method further argues that the mere existence of a listing for a product in a pharmaceutical drug database is not a representation of current commercial availability, and that at least one pharmaceutical industry representative deposed by Concordia testified that it was common to find a database listing for a product that was not yet commercially available. See Defs.' Mem. in Opp'n to Pl.'s Mot. for Summ. J. Ex. I, Dep. of Lara Frick at 33 (“[I]n the past I’ve encountered drugs that were listed [in Medi-Span] that were not commercially available.”). Method notes that this is consistent with Concordia’s own pleadings, which indicate that databases are “used . . . to evaluate medications that are currently or will soon be on the market.” 3d Am. Compl. ¶ 30 (emphasis added).

Applying the appropriate standard of review, the court concludes that a genuine issue of material fact exists as to whether Method made literally false claims regarding availability when it listed the Me-PB-Hyos products. Although Method did not expressly indicate that Me-PB-Hyos would be commercially available as of June 1, 2014, reasonable minds could differ as to whether such message was “conveyed by necessary implication.” Scotts Co., 315 F.3d at 274.

Accordingly, a jury must decide whether Method made literally false statements regarding the availability of the Me-PB-Hyos products.

2. FDA Approval

Concordia also claims that Method made literally false statements indicating that the Me-PB-Hyos products had been approved by the FDA. To support this claim, Concordia points to the Me-PB-Hyos package inserts provided to Medi-Span, First Databank, and DailyMed, which included the following section on indications and usage:

Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the following indications as “possibly” effective: For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis

Pl.’s SUMF Ex. 1.

In response, Method argues that it never claimed that its own product, Me-PB-Hyos, had been approved by the FDA. Instead, Method specifically advised the listing services that Me-PB-Hyos had not received FDA approval. Method notes that before its products were ever listed with First Databank, Method advised the company that the Me-PB-Hyos products were unapproved. Likewise, the Medi-Span listing for Me-PB-Hyos indicated that its marketing category was “unapproved drug other.” Defs.’ SUMF Ex. K. As for the indications and usage section of the package inserts, Method argues that the phrase “this drug” encompasses all PBA drug products identical, related, or similar to Donnatal, and that the product labels and package inserts for other generic PBA drug products previously on the market contained similar language.

Based on the court’s review of the record, the court concludes that a factual dispute exists as to whether Method made literally false statements indicating that its Me-PB-Hyos products had

been approved by the FDA. Although Method expressly advised the listing services that its products had not been approved by the FDA, reasonable minds could differ as to whether FDA approval was conveyed by necessary implication as a result of the indications and usage section of the package inserts. Accordingly, a jury must decide whether Method made literally false statements regarding FDA approval.

3. Pharmaceutical equivalence

Concordia also claims that Method made literally false statements indicating that the Me-PB-Hyos products were pharmaceutically equivalent to Donnatal. Concordia emphasizes that the product labels and package inserts provided to the listing services indicated that Me-PB-Hyos tablets and elixir would contain the same active ingredients in the same amounts as Donnatal tablets and elixir. Because the Me-PB-Hyos products were not yet available at the time the labels and inserts were submitted by Method, Concordia argues that Method had no basis for the information contained in the labels and inserts, including the information indicating that the Me-PB-Hyos products were pharmaceutically equivalent to Donnatal.

In response, Method argues that the undisputed facts show that it intended to distribute a product that was pharmaceutically equivalent to Donnatal, and that it was making plans to do so before those plans were halted by this lawsuit. Method emphasizes that both it and Winder understood that Method intended to have Winder manufacture the pharmaceutical equivalent of Donnatal. See, e.g., Defs.' SUMF. Ex. B, Winder Rule 30(b)(6) Dep. 32 (“[W]e were contracted to make the pharmaceutical equivalent of Donnatal.”); Defs.' SUMF Ex. A, Tucker Dep. 79 (indicating that Tucker told Winder that he “wanted a product with the same ingredients as

Donnatal”). Method argues that there is no evidence that Me-PB-Hyos would not have been pharmaceutically equivalent to Donnatal, if Method had been able to follow through with its plans.

After considering the parties’ arguments, the court concludes that the issue of whether the product labels and package inserts contained literally false representations of pharmaceutical equivalence must be presented to the jury for determination and cannot be decided on summary judgment. The resolution of this issue hinges, to a certain extent, on whether Method falsely represented that the products were commercially available. If a jury finds that Method falsely represented that the Me-PB-Hyos products were commercially available when it listed the products, then the jury could also find that the descriptions of the products’ ingredients were literally false, since the products had not yet been manufactured. If, on the other hand, a jury finds that the listings for Method’s products did not imply that the products were commercially available, and merely indicated that Method intended to market a product that was pharmaceutically equivalent to Donnatal, then a jury could also find that Method’s claims regarding the ingredients of its planned products were not literally false.

4. Pricing

In its final claim of literal falsity, Concordia asserts that Method made literally false statements indicating that the Me-PB-Hyos products were priced lower than the Donnatal products. Because the Me-PB-Hyos products were not yet available at the time they were listed with Medi-Span and First Databank, Concordia argues that Method had no basis for the pricing information provided to the listing services.

In response, Method acknowledges that the pricing information provided to Medi-Span and First Databank indicated that the prices of Me-PB-Hyos products would be lower than the

prices of Donnatal products. However, Method argues that Concordia is unable to cite to any evidence demonstrating that the pricing information was false. Method emphasizes that it listed the prices at which it intended to offer Me-PB-Hyos products to customers, and that “it was just never able to actually offer the products at the proposed prices because Plaintiff, and this litigation, intervened.” Def.’s Mem. in Opp’n to Pl.’s M. for Summ. J. 25.

As was true with the issue of pharmaceutical equivalence, the court is of the opinion that the determination of whether Method provided literally false pricing information hinges on whether Method falsely represented that the Me-PB-Hyos products were commercially available. If a jury finds that the listings for Me-PB-Hyos tablets and elixir falsely represented that the products were commercially available, then the jury could find that the pricing information was literally false, since the products did not yet exist. If, on the other hand, a jury finds that the listings made no representation of commercial availability, and merely indicated that Method intended to market a product that was pharmaceutically equivalent to Donnatal, then the jury could also find that Method’s listed prices for the Me-PB-Hyos products were not literally false.

For these reasons, the court concludes that genuine issues of material fact exist with respect to whether Method made literally false statements regarding the Me-PB-Hyos products. Accordingly, neither side is entitled to summary judgment on this issue.

B. Materiality

Method also argues that, even assuming Concordia could prove that it made false statements regarding the Me-PB-Hyos products, the record establishes that any such statements were immaterial and, thus, that Concordia’s claim for false advertising fails at the second element. In response, Concordia argues that materiality can be presumed from a literally false statement,

and that the record nonetheless demonstrates that Method's allegedly false statements were material.

The United States Court of Appeals for the Fourth Circuit has not addressed the issue of whether materiality can be presumed when a statement is proven to be literally false. The court's review of the caselaw reveals that there is a split in the circuits on this issue. The Fifth Circuit, as Concordia notes in its briefs, has held that a plaintiff need not introduce evidence of materiality when the statement of fact at issue is shown to be literally false. See Pizza Hut, Inc. v. Papa John's Int'l, Inc., 227 F.3d 489, 497 (5th Cir. 2000); see also X-IT Prods., LLC v. Walter Kidde Portable Equip., Inc., 155 F. Supp. 2d 577, 630 (E.D. Va. 2001) (citing Pizza Hut, *supra*, for the proposition that a plaintiff "may not need to introduce evidence of materiality" if it "can prove to the satisfaction of the jury that the claims at issue are literally false"). On the other hand, the First, Second, and Eleventh Circuits have held that even when a statement is literally false, a plaintiff must still establish materiality. See Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242, 1250-51 (11th Cir. 2002) (recognizing the circuit split and electing to "stand with the First and Second Circuits, concluding that the plaintiff must establish materiality even when a defendant's advertisement has been found literally false").

At this stage of the proceedings, the court will assume, without deciding, that the Fourth Circuit would concur with the position of the First, Second, and Eleventh Circuits, and hold that a plaintiff must establish materiality even when a defendant's advertisement has been found to contain a literally false statement. For the following reasons, however, the court concludes that the evidence cited by Concordia creates a genuine dispute of fact with respect to the element of materiality and, thus, that Method is not entitled to summary judgment on Count I.

As set forth above, the materiality prong requires the plaintiff to demonstrate that the defendants' false statements or representations were likely to influence purchasing decisions. Scotts Co., 315 F.3d at 272. In this case, a reasonable jury could find that a representation of pharmaceutical equivalence would likely influence purchasing decisions, because it "relates to an inherent quality or characteristic of the product." Cashmere, 284 F.3d at 312; see also Rexall Sundown, Inc. v. Perrigo Co., 651 F. Supp. 2d 9, 30 (E.D.N.Y. 2009) (holding that summary judgment on the issue of materiality was unwarranted since "a rational trier of fact could conclude that the disputed issues relate to core ingredients and/or efficacy"); Merck Eprova AG v. Gnosis S.P.A., 901 F. Supp. 2d 436, 451 (S.D.N.Y. 2012) (emphasizing that "the very nature of what a manufacturer is selling is material"). Likewise, a reasonable jury could find that representations regarding a pharmaceutical product's price, approval, and availability would likely influence purchasing decisions in the relevant market. See, e.g., North Am. Med. Corp. v. Axiom Worldwide, Inc., 522 F.3d 1211, 1226 (11th Cir. 2008) (observing that a false claim of FDA approval "logically would influence a doctor's decision to purchase [a device] over a competing machine without [that] qualit[y]"); PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 932 (9th Cir. 2010) (noting that an intentional misrepresentation regarding a product's release date might persuade purchasers not to buy a device that is already available). Accordingly, summary judgment is not appropriate on this element.

C. Consumer deception

The third element of a claim for false advertising under the Lanham Act requires a plaintiff to demonstrate that the alleged false statement actually deceived or had the tendency to deceive a substantial segment of the plaintiff's audience. Scott's Co., 315 F.3d at 272. "[T]he evidence

required of a false-advertising plaintiff is dependent upon whether the case involves advertising that is literally false or advertising that is only impliedly false.” Id. at 274. If the advertising at issue is literally false, consumer deception is presumed and, thus, “no evidence of consumer confusion is required.” Id. If, on the other hand, the plaintiff’s theory of recovery is based upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged advertisements tend to confuse consumers. Id. at 273.

To the extent Method seeks summary judgment on the basis that Concordia is unable to establish the element of consumer deception, Method’s motion must be denied. For the reasons set forth above, the court is of the opinion that a reasonable jury could find that Method made literally false statements regarding the Me-PB-Hyos products. Because Concordia “may benefit from a presumption of consumer deception” at trial, summary judgment is inappropriate. Cashmere, 284 F.3d at 316.

D. Distribution in interstate commerce

The fourth element of a claim for false advertising under the Lanham Act requires a plaintiff to demonstrate that Method placed the allegedly false statements in interstate commerce. Scotts Co., 315 F.3d at 272. To the extent Method seeks summary judgment on the basis of this element, the motion must be denied. The database listings for Method’s Me-PB-Hyos products were placed on the internet at the defendants’ behest. “The internet is considered an ‘instrumentality of interstate commerce,’ and as such, satisfies the fourth element” of the test for false advertising. Verisign, Inc. v. XYZ.com, LLC, No. 1:14-CV-01749, 2015 U.S. Dist. LEXIS 157471, at *12 (E.D. Va. Nov. 20, 2015) (quoting AvePoint, Inc. v. Power Tools, Inc., 981 F.

Supp. 2d 496, 512 (W.D. Va. 2013)). Accordingly, Method is not entitled to summary judgment on this ground.

E. Injury and Causation

The final element of a claim for false advertising under the Lanham Act requires the plaintiff to demonstrate that it has been or is likely to be injured as a result of the allegedly false advertising. Scotts Co., 315 F.3d at 272. In moving for summary judgment based on this element, Method argues that Concordia's profits from the sale of Donnatal increased after the listings for Me-PB-Hyos appeared and, thus, that Concordia is unable to show that it has been or is likely to be injured by any alleged misrepresentation made in conjunction with the listings. In response, Concordia argues that injury is presumed in cases involving representations that are literally false, and that even without the benefit of such presumption, the record demonstrates that Method's allegedly false statements are likely to cause, and have actually caused, damage to Concordia.

The Fourth Circuit has yet to decide whether and under what circumstances a presumption of harm should be applied in false advertising cases under the Lanham Act. See id. at 273 (expressly declining to decide these issues); Pharmanetics, Inc. v. Aventis Pharms., Inc., 182 F. App'x 267, 273 (4th Cir. 2006) (assuming, without deciding, that a presumption of harm applied in a false advertising case in which the defendant's statements were found to be literally false, but nonetheless affirming the grant of summary judgment where there was no evidence as to the extent of the plaintiff's damages). In the instant case, the court concludes that, even without the benefit of a presumption, Concordia has produced sufficient evidence to create a genuine dispute regarding the likelihood of injury.

For purposes of establishing liability for a violation of the Lanham Act’s false advertising provision, “[t]he statute demands only proof providing a reasonable basis for the belief that the plaintiff is likely to be damaged as a result of the false advertising.” Johnson & Johnson v. Carter-Wallace, Inc., 631 F.2d 186, 190 (2d Cir. 1980); see also 15 U.S.C. § 1125(a) (false advertising claim may be brought “by any person who believes that he is or is likely to be damaged” by the use of a false or misleading description of fact). Thus, for liability purposes, the appropriate standard is whether it is likely that Method’s advertising has caused or will cause a loss of sales, not whether Concordia has come forward with specific evidence that Method’s advertising actually resulted in some definite loss of sales. Id.; see also Cashmere, 284 F.3d at 318 (“A precise showing of [actual harm] is not required, and a diversion of sales, for example, would suffice.”) (internal citation and quotation marks omitted).

To satisfy this element, Concordia has proffered evidence demonstrating that members of the pharmaceutical industry relied upon the information contained in the listings for Me-PB-Hyos, and treated Me-PB-Hyos as a generic alternative to Donnatal. As a result, Me-PB-Hyos was linked to Donnatal as an available product in the dispensing software utilized by pharmacies, including the software utilized by Rite-Aid.

Concordia has also produced Symphony data indicating that by the week ending June 13, 2014, pharmacists were already submitting, and third-party payors were approving, claims for Me-PB-Hyos. The Symphony data also reveals instances where insurance coverage claims for Donnatal were refused while claims for Me-PB-Hyos were approved. Additionally, in at least one case, Donnatal was actually removed from an insurance company’s formulary with Me-PB-Hyos listed as the preferred alternative.

Concordia has also produced evidence demonstrating that doctors eventually stopped prescribing Donnatal based on the mistaken belief that it was unavailable or could no longer be dispensed by a pharmacy. For instance, Colleen Nakumura testified that she slowly stopped writing prescriptions for Donnatal after being told that Donnatal was no longer available for dispensing. Nakumura estimated that approximately twelve or fourteen prescriptions were turned down in the first month after the availability issue arose. Concordia emphasizes that Nakumura's testimony is consistent with weekly prescription data obtained from Symphony, which indicates that prescriptions for Donnatal began to drop almost immediately after the listings for Me-PB-Hyos products were added to the pharmaceutical databases.

In response, Method challenges the admissibility of the Symphony data on the basis that Deborah Drake, the Symphony representative who provided a declaration in support of the report's admission, testified at her deposition that she did not have personal knowledge of the factual data contained in the report. As Concordia notes in reply, however, it is clear from Drake's declaration and deposition testimony that she personally examined the Symphony report. Thus, to the extent Method objects to the admissibility of the report under Federal Rule of Evidence 602, the court agrees with Concordia that Drake's personal examination of the report is sufficient to satisfy the rule's personal knowledge requirement. See, e.g., Bryant v. Farmers Ins. Exch., 432 F.3d 1114, 1123 (10th Cir. 2005) ("Since [the auditor] personally examined these audit reports, she had personal knowledge of their content [for purposes of Rule 602].").

With respect to the links to Me-PB-Hyos in Rite-Aid's dispensing software, Method emphasizes that the same employee who relayed this information to Concordia advised that "generic encroachment on Donnatal . . . is not an issue with CVS, Walmart [or] Walgreens," and

that “Donnatal was pulled up with no generic product showing” at each of those pharmacy chains. Pl.’s SUMF Ex. 82. Additionally, the Concordia employee further relayed that if Me-PB-Hyos was ordered first by Rite-Aid pharmacists, the pharmacists would “get a response of ‘NOT AVAILABLE’ on their computer screen.” Id.

Method further argues that neither the Symphony data nor Nakumura’s testimony provides a sufficient link between alleged consumer confusion and any alleged false or misleading statement by Method. With respect to Nakumura’s testimony, Method emphasizes that Nakumura indicated that she was told that Donnatal was no longer being made. Method notes that Donnatal Extentabs had, in fact, been discontinued a few years earlier, and that this could explain why Nakumura was advised by pharmacists that Donnatal was no longer available.

After considering the evidence presented by the parties, the court concludes that a genuine dispute of material fact exists as to whether Concordia has been injured by Method’s allegedly false representations. The representations were made when Method endeavored to list its Me-PB-Hyos products with the pharmaceutical databases, and it is undisputed that weekly prescription counts for Donnatal decreased after the Me-PB-Hyos listings appeared. While Method may ultimately convince a jury that the only connection between the listings and the decline in Donnatal prescriptions was a temporal one, and that the decline resulted from other factors, a reasonable jury could also find that Concordia was injured as a result of the representations at issue. Accordingly, Method is not entitled to summary judgment on this ground.

F. Extent of Concordia's damages

Method's final argument in support of its motion for summary judgment on the false advertising claim is that Concordia is unable to prove the extent of its damages with a degree of certainty that could support a jury verdict. In making this argument, Method relies on the reasons set forth in support of its motion to exclude Concordia's damages expert, Ivan Hoffman.

As will be explained in a separate memorandum opinion, portions of Hoffman's damages report must be excluded, including Hoffman's conclusions regarding the total amount of lost profit damages incurred by Concordia. However, this does not signify that Concordia's claim for damages necessarily fails. Concordia can still rely on sales and prescription data, anecdotal evidence, and the factual testimony of Hoffman and other witnesses to support its claim for damages. Accordingly, the court's decision to limit the opinions offered by Hoffman does not necessarily prevent Concordia from proving its damages with reasonable certainty. Ultimately, the court is convinced that the extent of any damages suffered by Concordia is a question of disputed fact that is best left to the jury to decide.

For all of these reasons, neither side is entitled to summary judgment on Concordia's claim for false advertising under the Lanham Act. Accordingly, the cross-motions for summary judgment will be denied with respect to this claim.

II. Unfair Competition Claim

In Count II of the third amended complaint, Concordia asserts a claim for "unfair competition in violation of Section 43(a) of the Lanham Act." 3d Am. Compl. ¶ 67. Concordia alleges that "Donnatal has become uniquely associated with and identifies Plaintiff[] as the only FDA-approved provider[] of PBA pharmaceuticals," and that Method's "representations that

Me-PB-Hyos is pharmaceutically equivalent to Donnatal, and is an FDA-approved PBA pharmaceutical, have deceived, misled and confused consumers and enabled Defendants to trade off of Plaintiff[s] reputation and goodwill.”⁵ Id. ¶ 66.

In moving for summary judgment on this claim, Method argues, as it did with respect to the claim for false advertising, that it made no false statements regarding pharmaceutical equivalence or FDA approval. For the reasons set forth above, the court is convinced that a genuine dispute of material fact exists with respect to this issue. Accordingly, Method is not entitled to summary judgment on Count II.

III. Violation of the Virginia Consumer Protection Act

In Count III, Concordia alleges that Method violated the Virginia Consumer Protection Act (“VCPA”) by falsely representing that Me-PB-Hyos is pharmaceutically equivalent to Donnatal and approved by the FDA. Method has moved for summary judgment on this claim. Method argues that Concordia is not eligible for relief under the VCPA, because this case does not involve the type of consumer transaction contemplated by the statute. For the following reasons, the court agrees.

The VCPA prohibits “a supplier in connection with a consumer transaction” from misrepresenting “the source, sponsorship, approval or certification of goods or services,” or “that goods or services have certain quantities, characteristics, ingredients, uses, or benefits.” Va.

⁵ Based on the facts alleged in support of Count II, it appears that the claim is technically one for false association in violation of § 43(a)(1)(A) of the Lanham Act. As the Fourth Circuit recently explained, “§ 43(a) sets forth unfair competition causes of action for false association and false advertising.” Belmora LLC v. Bayer Consumer Care AG, ___ F.3d ___, 2016 U.S. App. LEXIS 5380, at *11-12 (4th Cir. Mar. 23, 2016). “Subsection A [of § 43(a)(1)], ‘which creates liability as to ‘affiliation, connection, or association’ of goods, describes the cause of action known as ‘false association.’” Id. “Subsection B, which creates liability for ‘misrepresent[ing] the nature, characteristics, qualities, or geographic origin’ of goods, defines the cause of action for ‘false advertising.’” Id.; see also Lexmark Int’l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1384 (2014) (observing that § 43(a) of the Lanham Act “creates two distinct bases of liability: false association, and false advertising”) (internal citations omitted).

Code § 59.1-200(A). In enacting the VCPA, the Virginia General Assembly intended that it “be applied as remedial legislation to promote fair and ethical standards of dealings between suppliers and the consuming public.” Va. Code § 59.1-197.

Based on the expressed purpose of the statute, courts have repeatedly held that the VCPA “is designed to provide members of the consuming public, not commercial competitors, with a statutory remedy” and, thus, that competitors “lack standing to prosecute a claim under the VCPA.” Diamonds Direct USA, Inc. v. BFJ Holdings, Inc., No. 3:12CV303-HEH, 2012 U.S. Dist. LEXIS 90222, at *9-10 (E.D. Va. June 28, 2012); see also H.D. Oliver Funeral Apts., Inc. v. Dignity Funeral Servs., Inc., 964 F. Supp. 1033, 1039 (E.D. Va. 1997) (emphasizing that the intent of the VCPA is “to promote fair and ethical standards between suppliers and the consuming public,” and that “[a] competitor does not fit in that equation”); Microsoft Corp. v. #9 Software, Inc., No. 4:05cv106, 2005 U.S. Dist. LEXIS 36710, at *11 (E.D. Va. Dec. 15, 2005) (holding that a competitor lacked standing to sue under the VCPA); Portfolio Recovery Assocs., Inc. v. Portfolio Recovery Grp., LLC, No. 2:12cv649, 2013 U.S. Dist. LEXIS 150998, at *23 (E.D. Va. Oct. 28, 2013) (holding that the plaintiff was not entitled to default judgment on its claim under the VCPA, since the plaintiff did not allege that it was a consumer of the defendant’s services and instead alleged that the defendant was a competitor engaging in unfair competition).

In the instant action, Concordia does not claim that it was a potential consumer of Method’s Me-PB-Hyos products. Instead, Concordia asserts that it was the victim of unfair competition by Method. Consistent with the foregoing decisions, the court concludes that Concordia, as a commercial competitor, lacks standing to prosecute a VCPA claim in the instant action. Accordingly, Method’s motion for summary judgment will be granted as to Count III.

IV. Conspiracy Claims

In Count IV of the third amended complaint, Concordia asserts a common law conspiracy claim against the defendants. In Count V, Concordia asserts a related claim under the Virginia Business Conspiracy Act.

To prevail on the civil conspiracy claim, Concordia must show that “two or more persons combined to accomplish, by some concerted action, some criminal or unlawful purpose or some unlawful purpose by criminal or unlawful means.” Commercial Bus. Sys., Inc. v. BellSouth Servs., Inc., 453 S.E.2d 261, 267 (Va. 1995)). The foundation of a civil conspiracy claim is “the damage caused by the acts committed in pursuance of the formed conspiracy and not the mere combination of two or more persons to accomplish an unlawful purpose or use unlawful means.” CaterCorp, Inc. v. Catering Concepts, Inc., 431 S.E.2d 277, 281-82 (Va. 1993) (internal citation and quotation marks omitted).

Under the Virginia Business Conspiracy Act, injured parties can obtain treble damages against “[a]ny two or more persons who combine, associate, agree, mutually undertake or concert together for the purpose of . . . willfully and maliciously injuring another in his reputation, trade, business or profession by any means whatever.” Va. Code §§ 18.2-499 & 18.2-500. In order to prevail on its statutory conspiracy claim, Concordia must prove the following elements by clear and convincing evidence: (1) that the defendants agreed or conspired with another party or parties; (2) that the conspirators acted with legal malice, that is, intentionally, purposefully, and without lawful justification; and (3) that the intentional actions of the conspirators proximately caused injury to Concordia. DAG Petroleum Suppliers, LLC v. BP PLC, 268 F. App’x 236, 243 (4th Cir. 2008) (citing Simmons v. Miller, 544 S.E.2d 666, 676-77 (Va. 2001)).

In moving for summary judgment on the conspiracy claims, the defendants argue that the claims against Method and Tucker, Method's president, founder, and owner, are barred by the intracorporate immunity doctrine. Under this doctrine,

acts of corporate agents are attributed to the corporation itself, thereby negating the multiplicity of actors necessary for the formation of a conspiracy. In essence, this means that a corporation cannot conspire with its employees, and its employees, when acting in the scope of their employment, cannot conspire among themselves.

Baltimore-Washington Tel. Co. v. Hot Leads Co., LLC, 584 F. Supp. 2d 736, 744 (D. Md. 2008); see also Buffalo Wings Factory, Inc. v. Mohd, 622 F. Supp. 2d 325, 335 (E.D. Va. 2007). As Method emphasizes, the immunity afforded under this doctrine "is not destroyed even if [corporate] agents are sued in their individual capacity." Chaves v. McIntyre, 424 F. Supp. 2d 858, 861 (W.D. Va. 2006); see also Buschi v. Kirven, 775 F.2d 1240, 1251 (4th Cir. 1985) ("Simply joining corporate officers as defendants in their individual capacities is not enough to make them persons separate from the corporation in legal contemplation.").

In response to the defendants' motion, Concordia argues that its conspiracy claims are based, not on a conspiracy between Method and Tucker, but on a conspiracy between Method and Winder, the company that Method hoped would manufacture its Me-PB-Hyos products. Based on the evidence presented, however, the court concludes that this argument is without merit. While Concordia makes much of the fact that Winder knew that Method wanted it to manufacture a product that was pharmaceutically equivalent to Donnatal, Concordia has failed to explain how such knowledge on the part of Winder gives rise to an actionable conspiracy claim. It is undisputed that Method never paid Winder to manufacture a product that was pharmaceutically equivalent to Donnatal, and that no such product was ever manufactured by Winder. Moreover, the damages that Concordia claims in the instant action are alleged to have resulted from the

listings for Me-PB-Hyos in the pharmaceutical databases, rather than any action taken by Winder. Because the record is devoid of any evidence from which a reasonable jury could find that Winder had knowledge of Method's efforts to list the Me-PB-Hyos products, much less that Winder played a role in those efforts, the court concludes that any injury that Concordia may have suffered as a result of the listings is not actionable under the Virginia Business Conspiracy Act or the common law of conspiracy. Accordingly, Method's motion for summary judgment will be granted with respect to Counts IV and V.

V. Unjust Enrichment

In Count VI of the third amended complaint, Concordia asserts a claim for unjust enrichment. Unjust enrichment is an equitable theory of recovery "based upon an implied contract to pay the reasonable value of services rendered." Mongold v. Woods, 677 S.E.2d 288, 292 (Va. 2009). To recover under a theory of unjust enrichment, a plaintiff must prove: (1) that it "conferred a benefit on" the defendant; (2) that the defendant "knew of the benefit and should reasonably have expected to repay" the plaintiff for it; and (3) that the defendant "accepted or retained the benefit without paying for its value." Schmidt v. Household Fin. Corp., II, 661 S.E.2d 834, 838 (Va. 2008). The amount of recovery for unjust enrichment is limited to the value of the benefit gained by the defendant, regardless of the extent of the plaintiff's loss. See Metric Constructors, Inc. v. Bank of Tokyo-Mitsubishi, Ltd., 72 F. App'x 916, 923 (4th Cir. 2003); Quick Serve Concepts, LLC v. Cedar Fair, LP, 83 Va. Cir. 59, 67 (Va. Cir. Ct. 2011).

Applying these principles, the court concludes that Method is entitled to summary judgment on the claim for unjust enrichment. While Concordia argues that Method benefitted from being able to use the Donnatal product labels to create the labels for Me-PB-Hyos, there is no

evidence that Method accrued any value from this purported benefit. The undisputed evidence establishes that Method never manufactured or sold the Me-PB-Hyos products after they were listed, and, thus, that it made no profit from utilizing the Donnatal labels. Accordingly, the court is convinced that Method is entitled to summary judgment on Count VI. See, e.g., Schwasinger v. Price, 789 F. Supp. 347, 351 (D. Kan. 1992) (awarding summary judgment to the defendant on the plaintiff's claim for unjust enrichment where the defendants received no profits from the plaintiff's work and, thus, were not enriched by the plaintiff's efforts); Brenda Darlene, Inc. v. Bon Secour Fisheries, Inc., 101 So. 3d 1242, 1255 (Ala. Civ. App. 2012) (affirming the entry of summary judgment on the plaintiffs' unjust enrichment claim, where the plaintiffs presented no evidence regarding the value of the benefit received and retained by the defendants).

VI. Tortious interference

In the seventh and final count of the third amended complaint, Concordia asserts a claim for tortious interference with contract or business expectancy. To prevail on such claim, Concordia must prove: (1) the existence of a valid contractual relationship or business expectancy; (2) knowledge of that relationship or expectancy on the part of the interferor; (3) intentional interference inducing or causing a breach or termination of the relationship or expectancy; and (4) resulting damage to the party whose relationship or expectancy has been disrupted. Chaves v. Johnson, 335 S.E.2d 97, 102 (Va. 1985); see also Commerce Funding Corp. v. Worldwide Sec. Servs. Corp., 249 F.3d 204, 210 (4th Cir. 2001).

In moving for summary judgment on the claim for tortious interference, Method argues that there is no evidence of any specific contract or business expectancy with which Method allegedly interfered, much less any evidence that Method had knowledge of such specific contract

or expectancy. Absent such evidence, Method contends that it is entitled to summary judgment. For the following reasons, the court agrees.

“The purpose of laws against tortious inference is not to protect consumers or the operation of the marketplace generally.” Masco Contractor Servs. East, Inc. v. Beals, 279 F. Supp. 2d 699, 709 (E.D. Va. 2003). Instead, “these causes of action provide a legal remedy where a particular party’s specific, existing contract or business expectancy or opportunity has been interfered with in a tortious manner.” Id. (emphasis in original). Accordingly, the first element of a claim for tortious interference requires the plaintiff to establish the existence of a specific contractual relationship or business expectancy. Id.; see also 2-40 Virginia Model Jury Instructions – Civil Instruction No. 40.250 (requiring the plaintiff to prove “that there was a contract expectancy [prospective business relationship, or economic advantage; contract] between the plaintiff and (name of third party)”). Failure to prove a specific, existing contractual relationship or business expectancy is fatal to a tortious interference claim. See Masco, 279 F. Supp. 2d at 709; see also Gov’t Employees Ins. Co. v. Google, Inc., 330 F. Supp. 2d 700, 705-06 (E.D. Va. 2004) (“Because GEICO’s allegations are too broad and conclusory to plead a specific, existing contract or expectancy with a specific party, plaintiff’s claim for tortious interference with prospective economic advantage will be dismissed.”); Eurotech, Inc. v. Cosmos European Travels Aktiengesellschaft, 189 F. Supp. 2d 385, 391 (E.D. Va. 2002) (“Because plaintiffs do not identify the specific business relationships with which defendant has interfered, plaintiffs’ tortious interference claim fails.”).

In the instant case, Concordia has not cited to any specific contractual relationship or business expectancy with which Method knowingly interfered. Instead, relying on an affidavit

from Jean-Paul Laurin, the company's vice president of business development, Concordia argues that it has business and contractual relationships with unidentified "wholesalers and repackagers," and that it "expects to maintain continuing profits from these wholesalers and repackagers." Pl.'s SUMF Ex. 80. The court agrees with Method that such evidence is insufficient to establish the type of specific, existing contractual relationship or business expectancy required to sustain a claim for tortious inference. See, e.g., Advanfort Co. v. Int'l Registries, Inc., No. 1:15-CV-220, 2015 U.S. Dist. LEXIS 62125, at *12 (E.D. Va. May 12, 2015) (holding that the plaintiffs' allegations were insufficient to state a claim for tortious interference where the plaintiffs "failed to identify any specific contract or business expectancy" with which the defendants allegedly interfered and "instead only allege[d] that they 'had contractual relationships with various customers'") (emphasis in original). Accordingly, the court concludes that Method is entitled to summary judgment on Count VII.

Conclusion

For the reasons stated, Concordia's motion for summary judgment will be denied and Method's motion for summary judgment will be granted in part and denied in part. The Clerk is directed to send copies of this memorandum opinion and the accompanying order to all counsel of record.

DATED: This 29th day of March, 2016.

/s/ Glen E. Conrad
Chief United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CONCORDIA PHARMACEUTICALS, INC.,)
) Civil Action No. 3:14CV00016
Plaintiff,)
) **ORDER**
v.)
) Hon. Glen E. Conrad
METHOD PHARMACEUTICALS, LLC, et al.,) Chief United States District Judge
)
Defendants.)

This case is presently before the court on the parties' cross-motions for summary judgment. For the reasons stated in the accompanying memorandum opinion, it is hereby

ORDERED

as follows:

1. Concordia's motion for summary judgment is **DENIED**;
2. Method's motion for summary judgment is **GRANTED IN PART AND DENIED IN PART**; and
3. The case is will proceed to trial on Concordia's claims under the Lanham Act.

The Clerk is directed to send copies of this order and the accompanying memorandum opinion to all counsel of record.

DATED: This 29th day of March, 2016.

/s/ Glen E. Conrad
Chief United States District Judge