UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

EXEGI PHARMA, LLC,

Plaintiff,

v.

BROOKFIELD PHARMACEUTICALS, LLC,

Defendant.

Case No. 20-CV-192-JPS

ORDER

1. BACKGROUND

On February 7, 2020, Plaintiff ExeGi Pharma, LLC ("ExeGi") brought this suit against Defendant Brookfield Pharmaceuticals, LLC ("Brookfield"), alleging claims for (1) false advertising under 15 U.S.C. § 1125(a) (the "Lanham Act"); (2) unfair competition under the Lanham Act; (3) common law unfair competition; (4) fraudulent representation in violation of Wis. Stat. § 100.18 ("Section 100.18"); and (5) common law tortious interference with prospective contractual relations. ECF No. 1.

The case now comes before the Court on the parties' cross-motions for summary judgment. ECF Nos. 48, 53. Brookfield moves for summary judgment in its favor on all five of ExeGi's claims. ECF No. 49.[1] ExeGi moves

[1]While Brookfield purports to move for summary judgment on all five of ExeGi's claims, its briefing is devoid of any mention of even the elements of a Lanham Act unfair competition claim, or any application of the facts to those elements. Brookfield appears to group the Lanham Act claims together, but never outright explains whether the analyses as to both claims, for example, rise and fall together. It is also telling that ExeGi plainly moves only for summary judgment on the Lanham Act false advertising claim. Therefore, absent further explanation, the Court will deny Brookfield's motion for summary judgment as to ExeGi's Lanham Act unfair competition claim. *See Lexmark Intern., Inc. v. Static Control Components,*

for partial summary judgment in its favor with respect to liability on its claims for false advertising under the Lanham Act, common law unfair competition, and fraudulent representation in violation of Section 100.18. ECF No. 54. ExeGi also moves for a permanent injunction. ECF No. 54-1.

For the reasons set forth herein, Brookfield's motion for summary judgment will be granted in part and denied in part, ExeGi's motion for partial summary judgment will be granted in part and denied in part, and a permanent injunction will be entered by separate order in accordance with the holdings set forth herein.[2]

2. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56 provides that a court "shall grant summary judgment 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); *see Boss v. Castro*, 816 F.3d 910, 916 (7th Cir. 2016). A fact is "material" if it "might affect the outcome of the suit" under the applicable substantive law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248

Inc., 572 U.S. 118, 136 (2014) (explaining that "the Lanham Act treats false advertising as a form of unfair competition").

[2]The parties also submitted a plethora of motions to seal or restrict portions of their summary judgment briefing and exhibits thereto. ECF Nos. 47, 52, 78, 81, 89, 90. The information and documents subject to the motions to seal or restrict are legitimately confidential within the terms of the parties' Protective Order, ECF No. 27, the Federal Rules of Civil Procedure, and applicable case law. Therefore, the motions will be granted, and the Clerk of Court will be directed to maintain under seal and/or in restricted form the information and documents subject to the motions to seal.

The Court will also grant the parties' motions to seal or restrict portions of their briefing on ExeGi's motion to strike one of Brookfield's experts. ECF Nos. 72, 91, 96. The Court does not resolve the motion to strike at this juncture, as the Court does not rely upon any evidence relating to the disputed expert in deciding the summary judgment motions.

(1986). A dispute of fact is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*

The court construes all facts and reasonable inferences in the light most favorable to the non-movant. *Bridge v. New Holland Logansport, Inc.*, 815 F.3d 356, 360 (7th Cir. 2016). "The court must not weigh the evidence presented or determine credibility of witnesses; the Seventh Circuit instructs 'that [the court] leave[s] those tasks to factfinders.'" *H–D U.S.A., LLC v. SunFrog, LLC*, 311 F. Supp. 3d 1000, 1010 (E.D. Wis. 2018) (quoting *Berry v. Chi. Transit Auth.*, 618 F.3d 688, 691 (7th Cir. 2010)). "[T]he non-movant need not match the movant witness for witness, nor persuade the court that [its] case is convincing, [it] need only come forward with appropriate evidence demonstrating that there is a pending dispute of material fact." *Waldridge v. Am. Hoeschst Corp.*, 24 F.3d 918, 921 (7th Cir. 1994).

3. FACTUAL SUBMISSIONS

The parties submitted a stipulated, agreed-upon statement of facts. ECF No. 70. The Court adopts those stipulated facts that are *material* with minor, non-substantive edits, including omitting internal citations for brevity. Unfortunately, the parties submitted their facts with no logical narrative or order, which made reviewing the facts and supporting documentary evidence a cumbersome task. As a result, the Court has also taken liberties with reorganizing the facts into a more logical order and adding sub-sections. The Court has nonetheless taken care to avoid altering the substance of the parties' proffered undisputed facts. In the future, when before this branch of the Court, counsel should take care to submit their facts in a logical, narrative order.

The parties also submitted a joint statement of disputed facts, which outlines for the Court ten, itemized disputes of fact. The parties note therein that "[n]either party concedes the facts included herein are necessarily material or, if material, genuinely disputed." ECF No. 68 at 2 n.1. The Court notes in the "Analysis" section, *infra* Section 4, which proffered disputed facts it finds material and, if material, genuinely disputed. Those that the Court finds immaterial have been aside.

3.1 Material Undisputed Facts

3.1.1 Makeup of the Products

Probiotics are live bacterial cultures, similar to those normally present in the human gastrointestinal tract, which can have a beneficial effect on the host. ExeGi sells the probiotic product Visbiome. Brookfield states on its website that it "is an emerging, US, specialty pharmaceutical company focused on identifying, developing and marketing generic pharmaceutical products," and that it was founded "by a group of pharmaceutical executives with experience in generic OTC & branded products." Brookfield sells the probiotic product High Potency Probiotic ("HPP").

HPP is marketed and regulated as a food product. HPP is a food. HPP is a high potency probiotic food. HPP is not a drug and does not require a prescription. To the extent HPP is marketed as a medical food and deemed a medical food, it is required to be consumed under the supervision of a physician.

Beginning in 2017, Brookfield worked with a manufacturer of probiotics, UAS Laboratories, LLC ("UAS Labs"), to attempt to copy the formulation of Visbiome based on the formulation's patent, which expired in 2015. HPP is produced in a different manufacturing facility than

Visbiome, under different conditions. HPP was made with the same species of bacteria as were listed on the expired patent for the formulation of Visbiome plus an additional species of bacteria. Prior to the expiration of the patent, three of the strains listed in the patent were reclassified, however, as different strains from different species.[3] Thus, HPP has three species of bacteria not in the formulation of Visbiome, and Visbiome has one species of bacteria not in the formulation of HPP.

HPP and Visbiome do not contain all the same strains of bacteria.

HPP contains nine different bacterial strains of the following genus and species:	**Visbiome contains eight different bacterial strains of the following genus and species:**
Lactobacillus plantarum	Lactobacillus plantarum
Lactobacillus acidophilus	Lactobacillus acidophilus
Bifidobacterium lactis	Bifidobacterium lactis (two distinct strains)
Lactobacillus paracasei	Lactobacillus paracasei
Streptococcus thermophilus	Streptococcus thermophilus
Bifidobacterium breve	Bifidobacterium breve
Bifidobacterium longum	
Bifidobacterium infantis	
Lactobacillus bulgaricus	
	Lactobacillus helveticus

Thus, HPP contains several strains that are of an entirely different genus and species than the strains in Visbiome. In addition, there are nine

[3] "Many studies indicate that a bacterial species is composed of strains that are 70 to 100 percent related." Ellen Jo Baron, *Medical Microbiology* Chapter 3: Classification (4th ed. 1996), *available at* https://www.ncbi.nlm.nih.gov/books/NBK8406/ (last visited Mar. 8, 2023).

bacterial strains in HPP while there are eight in Visbiome. As such, the products are not the same.

Different strains of bacteria within the same genus and species can have different functionalities in and benefits to the human body, and can have widely differing performance characteristics and modes of action. As to the products at bar, HPP and Visbiome have sufficiently different metabolic profiles, meaning the two products are different. Specifically, HPP and Visbiome are genetically and biologically different. Brookfield explored changing its formula so that it would have eight strains, rather than nine, to better compare to VSL #3 (defined *infra* Section 3.1.2) and Visbiome.

3.1.2 History and Development of the Products

Visbiome is composed of a unique high-potency probiotic formulation of eight specific bacterial strains in precise proportions created by Professor Claudio De Simone ("Prof. De Simone") to manage numerous, persistent and often quite serious gastrointestinal diseases (the "De Simone Formulation"). The De Simone Formulation, sold by ExeGi in the United States as Visbiome, is one of the most extensively studied probiotics on the market, having been the subject of more than 70 human clinical trials.

The De Simone Formulation initially was sold by VSL Pharmaceuticals, Inc. ("VSL Inc."). Beginning in 2002, after Prof. De Simone decided to license (temporarily) the right to use his patent covering the De Simone Formulation to VSL Inc., the De Simone Formulation was commercially launched in the United States under the trademark "VSL #3." In the ensuing years, VSL Inc. sold VSL #3 with success. Dozens of human clinical trials of the De Simone Formulation were completed successfully, and the results of these studies were published in peer-reviewed medical

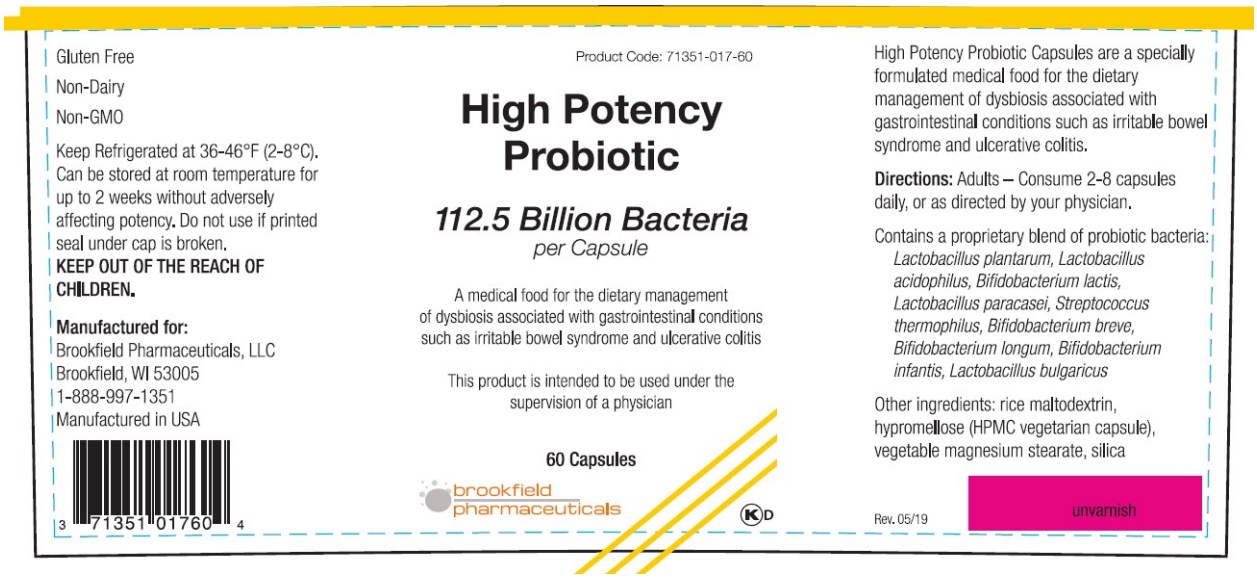
and scientific journals. Such trials demonstrated the safety and efficacy of the De Simone Formulation in the dietary management of, among others, inflammatory bowel diseases, irritable bowel syndrome, and Pouchitis.

Prof. De Simone resigned from VSL Inc. in November of 2014 and took with him the know-how that was necessary to manufacture the De Simone Formulation. A short time later, he exclusively licensed the right to sell and market the De Simone Formula to ExeGi.

ExeGi began selling the De Simone Formulation under the trademark "Visbiome" in February 2016. VSL Inc., meanwhile, created a new product—an imitation of the De Simone Formula that contained only seven strains (the "Fake Formula")—and, in June 2016, Leadiant Biosciences, Inc. ("Leadiant"), another licensee of VSL Inc., and Alfasigma USA, Inc. ("Alfasigma") began selling it under the same "VSL #3" trademark without informing the public that the formula had changed.[4]

[4]Prof. De Simone filed suit in the United States District Court for the District of Maryland, bringing various claims against VSL Inc., including a claim for a declaratory judgment that he owned the know-how. When ExeGi learned that Leadiant and Alfasigma were selling the seven-strain Fake Formula under the VSL #3 trademark, ExeGi joined the action and brought claims against Leadiant and Alfasigma for false advertising under the Lanham Act. The district court granted summary judgment for Prof. De Simone on the issue of know-how, ruling that Prof. De Simone owned it. Then, in November of 2018, after a three-week trial, the jury reached a unanimous verdict in favor of Prof. De Simone and ExeGi and against VSL, Inc., Alfasigma, and Leadiant. The jury awarded Prof. De Simone and ExeGi damages.

Brookfield began creating HPP in 2017. Brookfield attempted to make HPP "as comparable as possible" to Visbiome and VSL #3, and to "match" VSL #3's formulation "as closely as possible." Brookfield "formulated" HPP "as a generic to" Visbiome and VSL#3. The label for HPP is below:



The label for HPP does not list the exact quantity of each bacteria species on the product packaging. Further, the label for HPP does not list the strain designation of bacteria contained in the product.[5] The label for HPP notes that its blend of bacteria is proprietary. The label for HPP claims the product is a medical food for the dietary management of dysbiosis associated with gastrointestinal conditions such as irritable bowel syndrome and ulcerative colitis.

[5]Thus, as discussed more fully *infra* Section 3.1.3, the label appears to conflate bacteria "species" and "strains."

The label for HPP does not advertise HPP with any express assertion of validation by testing or study. The HPP packaging insert provides in part:

High Potency Probiotic Capsules are gluten free, non-dairy, non-GMO and Kosher certified.

High Potency Probiotic Capsules are labeled as a medical food as defined by the Orphan Drug Act and additional FDA regulations. Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of diet alone.[1] This medical food is not subject to NDA or ANDA approval and is not an Orange Book product. This product is intended to be used under active medical supervision.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

INDICATIONS AND USAGE

High Potency Probiotic Capsules are intended for the dietary management of individuals with distinct nutritional requirements relating to dysbiosis associated with GI conditions such as IBS and UC. High Potency Probiotic Capsules are a non-drug medical food that addresses distinct nutritional requirements to promote microbial balance in people with dysbiosis associated with IBS that cannot be achieved by modification of diet alone.

Maintenance of a healthy gut microbiota contributes to an overall healthy gastrointestinal environment.[2,3]

REFERENCES

1. United States Food and Drug Administration Title 21 Code of Federal Regulations 101.9(j)(8).
2. Chan, Y.K., et al. Clinical consequences of diet-induced dysbiosis. Ann Nutr Metab. 2013;63(suppl 2):28-40.
3. Whelan, K., Quigley, E M.M. Probiotics in the management of irritable bowel syndrome and inflammatory bowel disease. Curr Opin Gastroenterol. 2013;29(2):184-189.

Brookfield relies upon a summary of scientific literature to support its claim that HPP can be used for the dietary management of dysbiosis associated with gastrointestinal conditions such as irritable bowel syndrome and ulcerative colitis, as well as dossiers created by UAS Labs for each of the bacteria used in HPP. ExeGi agrees Brookfield relied upon this summary of scientific literature, but it takes the position that such reliance is inappropriate and unreasonable.

3.1.3 Representations Concerning the Products

In addition to the product label and insert, Brookfield has made the following statements regarding HPP directly to specific third-party individuals or entities:

(1) HPP is generic to Visbiome;

(2) HPP is comparable, comparable generic, or compares to Visbiome;

(3) HPP competes against Visbiome;

(4) HPP has the same GCN [defined *infra* note 6] as Visbiome;

(5) HPP contains the "same strains" as VSL#3 and Visbiome; and

(6) HPP has the "same probiotic bacteria" as Visbiome.

In August of 2018, Brookfield was still determining whether to market HPP as a medical food or a dietary supplement. Beginning in or around January or February of 2019, Brookfield began selling HPP. HPP is still sold today, principally through major wholesalers. Brookfield identified its primary customers for HPP as "the large pharmaceutical wholesalers"—namely, AmerisourceBergen, Cardinal Health, and McKesson—and "realized that this is a retail-focused product, so there may be opportunities at the large retailers, CVS, Walgreens, Costco, and Walmart. Our strategy was to put these products on what are known as generic source programs or their generic program contracts." These source programs provide pharmacists "rebates depending on whether they use the source product or they use a nonsource product," with the source products traditionally being generic products.

Brookfield did not advertise directly to clinicians or consumers, aside from the product label and package insert. ExeGi contends Brookfield advertised indirectly to clinicians and consumers through various

intermediaries. There is no evidence of a scientific survey of the relevant pharmaceutical industry participants as to whether any of Brookfield's alleged misrepresentations were material to and actually deceived consumers.

Brookfield has represented in communications directly to individual retailers, including Costco, that it has the "same strains" of bacteria as Visbiome and VSL #3. Most of the public and some clinicians incorrectly refer to genus and species as "strains." UAS Lab's corporate representative, Kevin Mehring ("Mehring") testified that it is probable that HPP has some of the same strains as Visbiome. Brookfield's Todd Graverson ("Graverson") testified that HPP and Visbiome contain the same strains, but then clarified that this statement was not intended to mean that the products contained "all of the same strains," but rather "many of the same strains."

Brookfield has instructed those taking questions regarding the similarities between HPP and VSL #3 or Visbiome to state the following: "Brookfield's High Potency Probiotic Capsules contains [sic] the same probiotic bacteria in the same total potency per capsule (112.5 billion bacteria) as (VSL #3 / Visbiome [call center to choose product according to the caller's question]). Since precise formulas are proprietary, we are unable to make an exact comparison to (VSL #3 / Visbiome [call center to choose product according to the caller's question])."

3.1.3.1 Representations to Drug Compendia

First Databank, Wolters Kluwer, Red Book, and Elsevier are national drug compendia. Drug compendia are companies that have databases that "maintain proprietary codes to group products based on specific ingredients and characteristics." These databases are disseminated widely

across the United States to distributors and retailers of medical products, as well as other key stakeholders in the healthcare industry including physicians and other healthcare providers. The drug compendia also group products based upon certain characteristics. First Databank, which is the largest of the drug compendia, groups drug and non-drug products under the same "GCN"[6] if they have the same active ingredients, dosage form, route of administration, and strength.

HPP and Visbiome were, at one time, grouped in the same GCN category by the First Databank and Wolters Kluwer drug compendia. Drug compendia rely on the information provided by drug and non-drug products' labels and package inserts. [redacted] Recently, First Databank modified its database, and the two products no longer are within the same GCN code.

Brookfield represented to First Databank on November 29, 2018 that HPP contains eight probiotic strains, rather than the nine it actually contains, which was corrected as of July 8, 2019, when a revised label with

[6]"GCN" stands for "generic code number." *See* Abramson, et al., *Generic Drug Cost Containment in Medicaid*, National Library of Medicine (Spring 2004), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194860/ (last visited Feb. 23, 2023).

nine strains was submitted. Brookfield represented to First Databank on the Standard Pharmaceutical Product Information (Rx Products Only) (referenced "HDA form") that its product is a "Generic Equivalent" of VSL #3 and Visbiome. Brookfield represented to First Databank that its product is a "medical food."

Brookfield represented to Wolters Kluwer on November 29, 2018 that HPP contains eight probiotic strains, rather than the nine it actually contains, which was corrected on July 8, 2019, when a revised label with nine strains was submitted. Only the nine-strain label of HPP was ever sent directly to any purchasers of the product. Brookfield represented to Wolter Kluwer on the HDA Form that its product is a "Generic Equivalent" of VSL #3 and Visbiome. Brookfield represented to Wolters Kluwer that its product is a "medical food."

Brookfield represented to Elsevier that HPP contains eight probiotic strains, rather than the nine it actually contains, which was corrected as of July 8, 2019 when a revised label with nine strains was submitted. Brookfield represented to Elsevier that its product is a "Generic Equivalent" of VSL #3 and Visbiome on the HDA form. Brookfield represented to Elsevier that its product is a "medical food."

Brookfield represented to Red Book that HPP contains eight probiotic strains, rather than the nine it actually contains, which was corrected as of July 8, 2019 when a revised label with nine strains was submitted. Brookfield represented to Red Book that its product is a "Generic Equivalent" of VSL #3 and Visbiome on the HDA form. Brookfield represented to Red Book that its product is a "medical food."

Graverson testified that listing VSL #3 and Visbiome as products to which HPP is a "generic equivalent" on the HDA form "point[s]" recipients

of the form "in the right direction of what these products are similar to." Graverson testified it is not accurate to refer to HPP as a generic equivalent of Visbiome because that term only has meaning in a drug context. ExeGi's expert, Alessio Fasano, has stated it is also inaccurate because HPP and Visbiome are "genetically [and] biologically . . . different."

3.1.3.2 Representations to Wholesalers

Brookfield represented to Cardinal Health that its product is a "Generic Equivalent" of VSL #3 and Visbiome on the HDA form. Brookfield represented to Cardinal Health that its product is a "medical food." Brookfield's HPP is listed as a "Suggested Alternate" to VSL #3 in Cardinal Health's ordering system.

Additionally, Brookfield represented to ClarusOne that HPP is a "generic to" Visbiome and VSL#3. Brookfield also represented to AmerisourceBergen that HPP is a "medical food," and that it is a "Generic Equivalent" to Visbiome and VSL#3 on the HDA form.

Brookfield also submitted the HDA form, on which it listed VSL#3 and Visbiome as products to which HPP is a "generic equivalent" to McKesson. Brookfield wanted pharmacists who were buying probiotic products through McKesson to know that HPP is an available generic to VSL #3 and Visbiome as a lower cost alternative.

Once HPP was listed in the same GCN as Visbiome and VSL #3, Brookfield so informed McKesson. McKesson is a customer of First Databank and Wolters Kluwer and obtains medical product information through these databases. McKesson is the primary distributor through which Costco purchases medical products.

ExeGi's claimed special economic damages relate to sales of Visbiome made at Costco, which purchased HPP through McKesson.

Brookfield's HPP is listed as a "Gener. Equiv." to Visbiome in McKesson's Connect system. ExeGi did not have a contractual agreement with McKesson or Costco prior to or at the time of Brookfield's alleged misrepresentations. Brookfield's contract with McKesson was non-exclusive. Visbiome was ultimately added to McKesson in February of 2020 after working with an industry consultant.

3.1.4 FDA Authority Over Medical Foods

Brookfield markets its HPP product as a "medical food." HPP is manufactured at UAS Labs in Wausau, Wisconsin "as a Medical Food." VSL #3 is another high potency probiotic sold as a medical food, which competes with HPP and Visbiome.

The Food and Drug Administration ("FDA") differentiates between foods and drugs. Unlike a drug, a medical food cannot claim to prevent, treat, cure or mitigate the symptoms of a disease without making a drug claim that would require FDA approval. The term "medical food" has a statutory definition set out at 21 U.S.C. § 360ee(b)(3) as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

What constitutes an established "distinctive nutritional requirement" is not specifically defined by the FDA. The FDA issued proposed rulemaking for the regulation of medical foods in the November 29, 1996 Federal Register, wherein the FDA was seeking public comment on several items related to medical foods. The FDA specifically asked for public comment on an appropriate definition for "distinctive nutritional

requirement," but subsequently withdrew the proposed rulemaking in a November 26, 2004 Federal Register without providing response or enacting new medical food regulations. In this same Federal Register notice of proposed rulemaking, FDA asked for comment on the quantity and quality of scientific evidence which should be required to support the validity of claims made for medical foods. This question was also left unanswered when the proposed rulemaking was subsequently withdrawn. Neither the regulatory definition under 21 C.F.R. § 101.9(j)(8), nor the only FDA-issued guidance specific to medical foods addresses what is needed to substantiate medical food claims. Medical food claims must be substantiated. Such substantiation must be a study, studies, or scientific literature that provide adequate support for the claims made about the product.

Pursuant to this regulation, the FDA has authority to initiate enforcement actions against companies that make misbranded medical food products pursuant to this regulation, including issuing warning letters and ultimately seizing offending products. The "Medical Food Group" within the FDA can address a complaint about a misbranded product.

The FDA inspected the UAS Labs facility that was manufacturing HPP, and they requested HPP's label and packaging insert. The FDA has not initiated any enforcement action against Brookfield or UAS Labs as a result of its investigation.

The FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness, and provides therapeutic equivalence evaluations for approved multi-source prescription drug products. The Orange Book does not apply to medical foods.

No clinical trials have been performed on the HPP formulation as a whole. With regard to the nine individual strains of bacteria contained in HPP, there have been no clinical studies performed on five of those strains. Two studies have been conducted on the Bifidobacterium lactis strain in HPP, a single trial has been conducted on the Lactobacillus plantarum strain in HPP, two clinical trials have been conducted on the Bifidobacterium longum strain in HPP, and multiple clinical trials have been conducted on the Lactobacillus acidophilus strain in HPP.

4. ANALYSIS[7]

4.1 ExeGi's Lanham Act False Advertising Claim

To establish a claim for false advertising under the Lanham Act, a plaintiff must prove

> (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce;[8] and (5) the plaintiff has been or is likely

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[7]The parties hotly dispute whether Brookfield complied with the Local Rules on page length in its summary judgment moving brief, as well as whether Brookfield complied with the Court's summary judgment protocols, ECF No. 34, forbidding string citations and citations to more than 10 cases per legal claim. The Court will excuse Brookfield's oversized moving brief, as Brookfield uses several pages of its reply brief to explain its error. The Court reviewed all case law submitted by both parties, but focuses its analysis in this Order on the cases the parties addressed substantively, rather than in support of a legal standard or buried in a string cite. The Court will not wade into the parties' agreement or lack thereof to an extended reply brief schedule, but notes only, by way of additional comment, that Brookfield's reply brief was submitted in accordance with the timeline set by the Local Rules, while ExeGi's was not.

[8]Apart from its argument regarding whether the challenged statements are advertising or promotions, *see infra* Section 4.1.1, Brookfield does not dispute that

> to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a loss of goodwill associated with its products.

Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc., 388 F. Supp. 2d 967, 975–76 (E.D. Wis. 2005) (citing *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999)).

The lion's share of the parties' dispute boils down to three issues: (1) whether Brookfield's statements (except through the product label and packaging information) about which ExeGi complains were made in a "commercial advertisement or promotion" falling under the purview of the Lanham Act; (2) whether an analysis of the literal falsity of Brookfield's "medical food" statements on the product label and packaging information is precluded by the Food, Drug & Cosmetic Act ("FDCA"); and (3) whether Brookfield's other statements about HPP (except through the product label and packaging information) are literally false. After resolving these three questions, the Court turns to the remaining applicable portions of the five-factor *Hot Wax* analysis.

4.1.1 Commercial Advertisement or Promotion

As a threshold matter, the Court must determine whether Brookfield's statements (other than on its label and packaging, which the parties appear to agree qualify) qualify as "commercial advertisements" or "promotions." "[T]he mere act of placing a pharmaceutical product on the market, without more, cannot support a Lanham Act claim." *Par Sterile Prod., LLC v. Fresenius Kabi USA LLC*, No. 14 C 3349, 2015 WL 1263041, at *5 (N.D. Ill. Mar. 17, 2015). At the same time, "[a]dvertising or promotion" is

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its statements entered interstate commerce or otherwise respond to that portion of ExeGi's moving brief. ECF No. 54 at 14. Therefore, the argument is waived.

not "limited to published or broadcast materials." *Neuros Co., Ltd. v. KTurbo, Inc.*, 698 F.3d 514, 521 (7th Cir. 2012). "Advertising or promotion" requires "merely 'some medium or means through which the defendant disseminated information to a particular class of consumers.'" *Id.* (quoting *Podiatrist Ass'n, Inc. v. La Cruz Azul De P.R., Inc.*, 332 F.3d 6, 20 (1st Cir. 2003)). "[T]he required level of dissemination to the relevant purchasing public 'will vary according to the specifics of the industry.'" *Id.* (quoting *LidoChem, Inc. v. Stoller Enters., Inc.*, 500 F. App'x 373, 379 (6th Cir. 2012)).

The Seventh Circuit has made clear on one end of the scale that "just three examples of . . . person-to-person communications at trade shows" is not "advertising or promotion" within the meaning of the Lanham Act. *Sanderson v. Culligan Intern. Co.*, 415 F.3d 620, 624 (7th Cir. 2005). It has cited other jurisdictions favorably, however, for the propositions that "letters sent and statements made to distributors of farm chemicals," "an 'alert' sent only to large makers of air filters and the resellers of the filters," and "statements made only to one of two or three national refinancing committees" *are* "advertising or promotion," based on how the terms are analyzed in the context of the specific industry. *Neuros*, 698 F.3d at 523 (citing *LidoChem*, 500 F. App'x at 381; *Porous Media Corp. v. Pall Corp.*, 173 F.3d 1109, 1114 (8th Cir. 1999); *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999)). Indeed, the *LidoChem* court concluded that commercial speech was "advertising or promotion" when made for the purpose of influencing "not just the end-use farmer, but also the farm-chemical distributor." *LidoChem*, 500 F. App'x at 381.

This guidance leads the Court to conclude that Brookfield's statements are indeed advertising or promotion within the meaning of the Lanham Act. The parties' undisputed facts indicate that Brookfield

disseminated information about HPP to the three largest pharmaceutical wholesalers, as well as directly to individual retailers. For example, Brookfield informed McKesson once HPP was listed in the same GCN as Visbiome and VSL #3, and represented to Costco that HPP has the "same strains" of bacteria as Visbiome and VSL #3. Brookfield has identified McKesson as one of its primary customers, and has also described HPP as a "retail-focused product" and consequently sought "opportunities at the large retailers" including Costco. Brookfield also represented to drug compendia that HPP contains eight probiotic strains, and, through the HDA form, that its product is a "Generic Equivalent" of VSL #3 and Visbiome. Finally, Brookfield has utilized its call center to instruct callers that HPP contains "the same probiotic bacteria in the same total potency per capsule" as VSL #3 and Visbiome. There is no question that these communications constitute dissemination of information to a particular class of consumers—or here, classes: drug compendia, wholesalers, retailers, and end-use consumers. *See Neuros*, 698 F.3d at 521.

Brookfield cites to *Par Sterile Products* to support its argument that the communications at issue here were more akin to a "person-to-person pitch." 2015 WL 1263041, at *5. However, there, the court distinguished *Neuros* and *LidoChem* on the basis that those cases involved "disseminating false information about a competitor's product, albeit to a small class of consumers, to prevent consumers from trading with the competitor," rather than "misrepresentations made in the course of negotiating or executing a transaction with a particular purchaser." *Id.* at *6. The *Par Sterile Products* court found that the communications at issue there were purely contract negotiations, rather than advertising or promotion covered by the Lanham Act. *See id.* That is simply not the case here. Brookfield's communications

do not involve purely negotiation of individual contracts, but rather encompass a variety of media through which Brookfield represented information about HPP. The communications constitute advertising or promotions within the purview of the Lanham Act.

4.1.2 FDA and FDCA Preclusion

Brookfield next contends that "the falsity or misleading nature of [HPP's] label and packaging insert rises and falls on whether it is properly sold as a 'medical food.'" ECF No. 49 at 18. The parties in turn dispute whether an analysis of the falsity of the term "medical food" as used on HPP's label and packaging would be precluded by the FDCA.[9] ExeGi maintains that it is not asking the Court to determine whether or not HPP is a medical food, but whether Brookfield held HPP out as a medical food "despite having no data upon which to make such claims and affirmatively determining not to gather such data." ECF No. 82 at 21. ("In other words, ExeGi is not making a regulatory argument as to why HPP does not qualify for such designations; rather, it is pointing out that Brookfield's claims are false because they are wholly unsupported."). For its part, Brookfield argues that even an analysis as to "the substantiation required by the FDA" to sell a product on the market as a medical food would be precluded. ECF No. 49 at 14.

"When and if a claim strays too close to the exclusive enforcement domain of the FDA, it cannot stand." *Schwarz Pharma*, 388 F. Supp. 2d at 973

[9]The Court previously held in its order on Brookfield's motion to quash that "Plaintiff is entitled to discovery on both (1) whether Defendant considered HPP to be a medical food and (2) whether Defendant held HPP out as a medical food," but that "if the inquiry becomes whether HPP *is* a medical food, then it appears that the FDCA would preempt any analysis from the Court." ECF No. 46 at 7.

(internal citations omitted). "Such claims would allow a private litigant to interfere with the FDA's own investigatory time-table and prosecutorial decision-making." *Id.* (internal citations omitted). "However, the mere FDA regulation of a term does not necessarily bar all Lanham Act claims that pertain to that term . . . . Ultimately, there is no single, bright-line test to distinguish sustainable from non-sustainable claims." *Id.* (internal citations omitted).

As explained in the balance of this section, the Court finds that analyzing the quality of the data proffered by Brookfield in support of its claim that HPP is a medical food[10]—or even determining that there is no data at all, as ExeGi would have the Court find—would require it to analyze an area that the FDA has expressly held out as its own for rulemaking. A Lanham Act claim based on the argument that HPP's label or packaging as a "medical food" included a false or misleading statement is therefore precluded, and Brookfield's motion for summary judgment will be granted in this respect.

The regulatory record indicates that claims of whether a product is a medical food are the domain of the FDA. While the term "medical food" is defined by the FDCA, medical foods do not require FDA approval. The FDA has not issued any regulations or guidance that address what is needed to substantiate claims that a product is a medical food. *See* 21 C.F.R. § 101.9; 21 U.S.C. § 360ee(b)(3); Frequently Asked Questions About Medical Foods; Second Edition, Guidance for Industry, May 2016, *available at*

[10]For example, the parties submitted undisputed facts regarding studies conducted on certain strains of bacteria in HPP, though no clinical trials have been performed, and ExeGi disputes the quality of data presented in Brookfield's summary judgment briefing to further substantiate Brookfield's medical food claims. *See, e.g.*, ECF No. 82 at 25 n.6.

https://www.fda.gov (last visited Mar. 8, 2023). Indeed, as the parties note in their undisputed facts, *supra* Section 3.1.4, the FDA "asked for comment on the quantity and quality of scientific evidence which should be required to support the validity of claims made for medical foods" but the question was "left unanswered when the proposed rulemaking was subsequently withdrawn." *See Regulation of Medical Foods,* 61 Fed. Reg. 60661-01 (Nov. 29, 1996) ("The agency is concerned that many claims made for products marketed as medical foods are not supported by adequate scientific evidence."); *Withdrawal of Certain Proposed Rules and Other Proposed Actions*, 69 Fed. Reg. 68831-01 (Nov. 26, 2004) (withdrawing 61 Fed. Reg. 60661-01, but noting that "medical foods with false or misleading labeling are subject to enforcement action" in accordance with FDA's Medical Foods Compliance Program (CP.7321.002)).

The Court's conclusion is bolstered by the case law submitted by the parties. For example, ExeGi relies on *Solvay Pharmaceuticals, Inc. v. Ethex Corp.*, where the court reviewed a Fourth Circuit decision and summarized that decision as holding that whether tests supporting alleged bioequivalence were "falsified, unreliable, or non-existent . . . was a factual issue properly considered by the court." No. 03-CV-2836, 2004 WL 742033, at *3 (D. Minn. Mar. 30, 2004) (citing *Mylan Labs., Inc. v. Matkari*, 7F.3d 1130, 1138 (4th Cir. 1993)). However, in *Mylan*, the Fourth Circuit reversed the district court at the motion to dismiss stage, finding that these allegations of falsity or lack of reliability *at the pleadings stage* were sufficient. *Mylan*, 7 F.3d at 1138. The Fourth Circuit further explained that "in order ultimately to succeed on its Lanham Act count, [the plaintiff] will have to show more evidence than mere proof that the defendants' claims were supported by unpersuasive test results." *Id.* "Rather, the plaintiff must demonstrate that

such tests are not sufficiently reliable to permit one to conclude with reasonable certainty that they established the claim made." *Id.* (internal citations omitted).

This is where preclusion comes into play. In the context of medical foods, as explained above, there is no metric to which the Court can compare the data before it. To analyze the literal falsity of Brookfield's medical foods claim, the Court would be "interpret[ing] . . . a matter that is exclusively within the jurisdiction and expertise of the FDA and FDCA." *Solvay*, 2004 WL 742003, at *3. This the Court will not do. *See also Sandoz Pharma. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("The FDA has not found conclusively that demulcents must be labelled as active or inactive ingredients . . . . We decline to find and do not believe that the district court had to find . . . that which the FDA, with all of its scientific expertise, has yet to determine.").

By way of further example, ExeGi also relies on *Grove Fresh Distributors, Inc v. Flavor Fresh Foods, Inc.* for the proposition that reliance on an FDA definition for a Lanham Act claim is sustainable where such reliance is "merely to establish the standard or duty which defendants allegedly failed to meet." 720 F. Supp. 714, 715–16 (N.D. Ill. 1989). Again, such a standard or duty for what is required to substantiate a medical food claim has not yet been promulgated by the FDA. The definition of "medical food" in the FDCA does not provide such a standard. The FDA, nonetheless, retains the authority to initiate enforcement actions against companies that make misbranded medical food products. *See Withdrawal of Certain Proposed Rules and Other Proposed Actions*, 69 FR 68831-01; FDA's Medical Foods Compliance Program (CP.7321.002) (implemented Aug 24, 2006), *available at* https://www.fda.gov (last visited Mar. 8, 2023) (detailing

inspection procedures and noting that "[p]otential problems may also be associated with labeling claims if clinical indications for use or compositional descriptions are not adequately supported by appropriate data").

Under these circumstances, it appears that ExeGi's "position would require [the Court] to usurp agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." *Sandoz*, 902 F.2d at 231; *see also PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 926 & 928 (9th Cir. 2010) (declining to consider Lanham Act claim where relevant "issue was presented to the FDA, but it does not appear that the agency ever reached [a] conclusion"; also collecting cases holding that courts should not preemptively determine how a federal agency will interpret and enforce its own regulations). While ExeGi argues that Brookfield's use of the term "medical food" was purely for marketing, ECF No. 82 at 26, it does not cite any case law supporting that such an argument can salvage a FDCA preclusion issue. Accordingly, Brookfield is entitled to summary judgment on this issue; any Lanham Act claim as to the "medical food" claims on HPP packaging is precluded at this juncture and will be dismissed without prejudice.[11]

[11]For the same reason, the Court will dismiss without prejudice ExeGi's Section 100.18 claim. The parties' main dispute as to that claim is whether HPP is a food product. ECF No. 49 at 29; ECF No. 82 at 32. Even if the Court were to analyze Section 100.18 and its "food" counterpart, Section 100.183, to determine whether there is a "conventional food" versus "non-conventional food" distinction, to resolve the claim, the Court would, in substance, be making a determination as to whether HPP is a "non-conventional food" or a dietary supplement. *See, e.g.*, *Standard Process, Inc. v. Total Health Discount, Inc.*, 559 F. Supp. 2d 932, 940 (E.D. Wis. 2008) (applying Section 100.18 to dietary supplements). Such a determination veers uncomfortably close to a determination as to whether HPP is a medical food, which determination the Court has already held to be precluded.

4.1.3 Literal Falsity of Statements Other Than "Medical Food" Claims on HPP Packaging

The Court has determined that Brookfield's statements other than on its packaging (which the parties concede is an advertisement or promotion) constitute advertisements or promotions, and that "medical food" claims as to HPP's packaging are precluded. The Court now turns to whether Brookfield's statements (except through the product label and packaging information) are literally false.

"A 'literal' falsehood is bald-faced, egregious, undeniable, over the top." *Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 512 (7th Cir. 2009). "[P]roof of literal falsity allows the plaintiff to dispense with evidence that anyone was misled or likely to be misled," which is the second factor in the *Hot Wax* test, set forth above. *Id.* As the Seventh Circuit has explained, "[t]he proper domain of 'literal falsity' as a doctrine that dispenses with proof that anyone was misled or likely to be misled is the patently false statement *that means what it says to any linguistically competent person*." *Id.* at 513 (emphasis added).

By way of example, the Seventh Circuit offered the 1930s Soviet Union slogan "2 + 2 = 5," explaining that, while literally false, the statement was not intended to and did not deceive anyone, rather "it was announcing a slogan designed to spur workers to complete the Five-Year plan in four years." *Id.* at 512. A linguistically competent person would understand that such a statement does not mean what it literally says; therefore, the statement is not "false and misleading per se," and courts must continue the analysis and "consider context or audience" to determine whether

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See supra n.9. Indeed, the argument is puzzling to begin with given that the parties submit as an undisputed fact that "HPP is a food." ECF No. 70 at 2.

anyone was misled or likely to be misled by the statement. *Id.* at 513. On the other hand, for example, a statement on a label that a drug can be sold only by prescription, when in reality there is an over-the-counter version of the drug, means what it says when read by a linguistically competent person and is false and misleading per se. *Id.* Under these circumstances, there is no need to consider context or audience. *Id.*

The parties generally group their arguments as to whether the statements are literally false into two categories: (1) Brookfield's claims that HPP has the "same probiotic bacteria" and the "same strains" as Visbiome; and (2) Brookfield's claims that HPP is a "generic equivalent" of and "generic" to Visbiome.

4.1.3.1 "Same Probiotic Bacteria" or "Same Strains"

Brookfield argues that its statements that HPP has the "same probiotic bacteria" and the "same strains" as Visbiome are not literally false for several reasons. First, Brookfield contends that for the Court to determine that the statements are literally false would only be possible "by ignoring the context in which the statements were made," contrary to Seventh Circuit case law. ECF No. 88 at 7 (citing *Schering-Plough*, 586 F.3d at 513). However, as the Court explained, it does not read *Schering-Plough* in this manner; *Schering-Plough* expressly instructs that context or audience should not be considered if a statement means what it says to a linguistically competent person, and what it says is false or misleading per se. Brookfield appears to concede as much pages later in its brief. ECF No. 88 at 11 (arguing a statement is not literally false because it is not "so obviously misleading that there is no need to gather evidence that anyone was confused") (citing *Schering-Plough*, 586 F.3d at 513).

Second, Brookfield argues that its use of the word "same" was not intended to mean "all of the same strains," but rather "many of the same strains." *Id.* at 7; ECF No. 49 at 25 (citing *Black's Law Dictionary*, 4th Ed. (West 1968) and *The Merriam Webster Dictionary*, 1st Pocket Ed. (G & C Merriam Co. 1974) for the propositions that "same" means "a kind" or "similar")). The Court disagrees. The most recent editions of Black's Law Dictionary and The Merriam Webster Dictionary define "same" as "identical or equal; resembling in every relevant respect" and "resembling in every relevant respect; being one without addition, change, or discontinuance," respectively. *Black's Law Dictionary*, 11th Ed. (West 2019); *The Merriam Webster Dictionary*, *available at* https://www.merriam-webster.com/dictionary/same (last updated by eds. Mar. 4, 2023) (last visited Mar. 8, 2023).

The parties do not dispute that HPP contains nine bacterial strains, while Visbiome contains eight. They do not dispute that HPP contains several strains that are of an entirely different genus and species than the strains in Visbiome. Indeed, as an undisputed fact, they submit verbatim that "the products are not the same." ECF No. 70 at 10. They do not dispute that different strains of bacteria within the same genus and species can provide different benefits to the human body, function differently in the human body, and have "widely differing" performance characteristics and modes of action, as well as "sufficiently different" metabolic profiles. *Id.* at 9, 10, 18. Finally, they do not dispute that Visbiome is comprised of the De Simone Formulation and has been the subject of over 70 human clinical trials, while HPP is not and has not. *Id.* at 3, 11.

In *Schering-Plough*, the Seventh Circuit cited *Abbott Laboratories v. Mead Johnson & Co.* as providing an example of "a representation [that is]

so obviously misleading that there is no need to gather evidence that anyone was confused." 586 F.3d at 512 (citing *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 13–14 (7th Cir. 1992)). There, the court held that a description of a product as a "rice-based oral electrolyte solution" was literally false where the product did not contain powdered whole rice or rice carbohydrates, but rather contained rice syrup solids. *Abbott Labs.*, 971 F.2d at 13. Those two additives "are a completely different animal . . . and yield few if any of the [same] benefits." *Id.* Similarly, the parties here do not dispute that the bacterial contents and metabolic profiles of Visbiome and HPP (not to mention each product's clinical testing, or lack thereof) are different. It is wholly clear to the Court that, given the undisputed facts, using the word "same" to describe HPP and Visbiome is a literal falsity. *Schering-Plough*, 586 F.3d at 512–13 ("'[L]iteral' must be understood in the common colloquial sense in which Americans . . . say things like 'I am literally out of my mind.'").

Brookfield's third argument is premised on the fact that the parties do not dispute that most of the public and some clinicians incorrectly refer to genus and species as "strains." ECF No. 88 at 9. Unlike Visbiome, HPP's label identifies only the bacteria species and not the strains. By comparing the two labels, Brookfield argues, a recipient can see that the products have some of the same species and do not reference the strains. *Id.* at 10. Therefore, Brookfield's statements that HPP and Visbiome have the same strains, which it contends was based off of the label and therefore a misunderstanding, is not literally false. The Court is not persuaded by this highly circuitous and tortured argument. Even if the Court were to be convinced that Brookfield meant to say the "same species" instead of the

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"same strains," that statement would still be literally false, as the parties do not dispute that HPP and Visbiome contain bacteria of different species.

Brookfield asks the Court not to adopt ExeGi's "interpretation" of the phrases "the same probiotic bacteria" and "the same strains," contending that doing so would require the Court to violate accepted tenets of language interpretation by inserting the word "all"; that is, reading the phrases instead as "all the same probiotic bacteria" and "all the same strains." ECF No. 88 at 10. However, it is *Brookfield* that asks the Court to insert words that are not there by urging a reading of the word "same" as "many of the same" or "some of the same." Brookfield's support therefor is based on outdated dictionaries[12] and defies common sense. In the Court's view, the word "same" unambiguously and unequivocally means "identical" or "equivalent" and, based on the undisputed evidence before it, "could not reasonably be understood to mean anything different." *Mkt. Track, LLC v. Efficient Collaborative Retail Mktg., LLC*, No. 14 C 4957, 2015 WL 3637740, at *21 (N.D. Ill. June 11, 2015). ExeGi's false advertising Lanham Act claim as to the "same probiotic bacteria" and the "same strains" statements may proceed to the next step of the *Hot Wax* analysis: materiality.

4.1.3.2 "Generic" or "Generic Equivalent"

The parties' dispute as to whether Brookfield's representations that HPP is a "generic" or a "generic equivalent" of Visbiome centers on the fact that the terms "generic" and "generic equivalent" fit within the regulatory

[12]Indeed, in other areas of its briefing, presumably where it better suits Brookfield's arguments, Brookfield cites the website version of Merriam Webster instead of the 1974 edition. *See, e.g.*, ECF No. 88 at 13.

framework for FDA-approved drugs, as opposed to products—like medical foods—that do not require FDA approval.

Brookfield, relying on *Steifel Laboratories, Inc. v. Brookstone Pharmaceuticals, L.L.C.*, argues that ExeGi has not performed any testing of the two products to determine whether they are or are not generics or generic equivalents of one another, and that ExeGi has not submitted evidence regarding the meaning of these terms in the context of non-drug products that are not subject to FDA approval. ECF No. 49 at 24–25 (discussing *Steifel Labs. v. Brookstone Pharms., L.L.C.*, No. 08-CV-3773, 2012 WL 12888436, at *8–*9 (N.D. Ga. July 24, 2012)).

At the outset, the Court agrees, as the *Steifel* court observed, that under these circumstances, "the showing of falsity is highly dependent on the context in which the advertisements were viewed." 2012 WL 12888436, at *9. "This is so because terms [such as] . . . 'generic' . . . have no meaning allowing an objective finding of literal falsity independent from that context." *Id.* In other words, the term "generic" is significantly different from the term "same," which the Court analyzed above. However, the contextual evidence in *Steifel* is readily distinguishable from the evidence here.

In *Steifel*, the plaintiff argued that "the *only* way to know whether [the products] are bioequivalent . . . is to perform scientific testing," but also conceded that it had performed no such testing. *Steifel*, 2012 WL 12888436, at *8 (emphasis added). Thus, "[a]ccording to its own argument, . . . the plaintiff has failed to produce the only evidence that can prove literally false the defendant's apparent claims of therapeutic equivalence." *Id.* The court also found that, given the importance of context to the inquiry, "even more troublesome for the plaintiff," the record was completely lacking on "what

the term [generic drug] means in the context of [products] not subject to FDA approval." *Id.* at *9. The court explained that "[a]t least one appropriate way to present evidence of the understanding of relevant pharmaceutical-industry players [of the term 'generic'] would be by presenting a scientific survey of those players." *Id.*

Here, ExeGi does not argue that testing of the products is necessary to assess whether they are properly dubbed generics or generic equivalents. And, importantly, the challenged statements themselves do not refer to testing. *Dyson, Inc. v. Sharkninja Operating LLC*, 259 F. Supp. 3d 816, 834 (N.D. Ill. 2017) ("If the evidence required to prove falsity is, as the Seventh Circuit says, to meet the substance of the claim, then a claim that the 'test proves x' is literally false only if the test does not (reliably) prove x."). Instead, as it did with the analysis as to the "same probiotic bacteria" or the "same strains," ExeGi hangs its hat on the fact that "HPP and Visbiome do not contain identical probiotic bacteria in terms of number of strains and genus and species of those strains, and even the probiotic bacteria of the same genus and species do not have matching strains." ECF No. 54 at 17–18.

ExeGi also offers multiple pieces of evidence supporting what the terms "generic" and "generic equivalent" mean in the non-drug context. For example, ExeGi's expert, Dr. Alessio Fasano, wrote that "[w]hen used to describe any product, including probiotic products, the term 'generic' is understood by physicians to mean that the product is equivalent to, and can be used and prescribed as a substitute for, another product." ECF No. 99 at 10 n.6 (citing ECF No. 58 at 6). Another expert, Professor Patrick Gillevet, opined that, if it applied to medical foods, the term "generic" could not apply to two products with "very different" "strain composition and

fermentation capacity." *Id.* at 10 n. 7 (citing ECF No. 66 at 13–14). Another expert, Melissa Krause, explained that calling a non-drug product the "generic equivalent" of another would be stating that the products are "substitutes for one another." *Id.* at 11.

Finally, ExeGi submits testimony regarding the method used by the drug compendia to assign the generic code numbers or "GCNs." ECF No. 54 at 26. Specifically, ExeGi submits testimony from Graverson that Brookfield went to the compendia with the goal that they assign the same GCN to HPP, Visbiome, and VSL #3. *Id.* [redacted] The parties do not dispute that while First Databank originally grouped HPP and Visbiome with the same GCN, it has since modified the database and the products no longer have the same GCN code.

With regard to the definition of "generic," by contrast, Brookfield cites to the Merriam Webster definition of "generic," which is defined as "not being or having a particular brand name." ECF No. 88 at 13 (citing https://www.merriamwebster.com/dictionary/generic). In the parties' joint statement of disputed facts, in support of its contention that HPP is a "generic" of Visbiome, Brookfield cites to: (1) Graverson's testimony that HPP could be characterized as a generic of Visbiome "[i]n the proper context," that is as a "lower-cost alternative of a similar product"; and (2) Brookfield's corporate representative, Brian Heinzelman's ("Heinzelman"),

testimony along the same lines. ECF No. 68 at 2. Brookfield also submits expert reports citing, for example, FDA definitions of "generic" indicating that "generic" means "comparable." *See, e.g.*, Expert Report of Sandra K.B. Kinsey ("Kinsey"), ECF No. 56-14 at 13–14 ("The same situation exists for probiotics.").

As to the definition of "generic equivalent," Brookfield argues that, by referring to HPP as a "generic equivalent" to Visbiome on the HDA form, it was trying to solve a "square peg/round hole" problem. ECF No. 88 at 15. Specifically, the form on its face applies only to prescription drug products, but nonetheless, Brookfield was required to use the form to have its product listed with the drug compendia. Therefore, Brookfield listed HPP as a "generic equivalent" of Visbiome on the form because it was filling out the form "the best [it] could." *Id.* As a result, Brookfield argues that, in this context, to call HPP a "generic equivalent" of Visbiome "can only be reasonably interpreted to mean that it is a product in the same product category as Visbiome, which is literally true." *Id.* at 16. However, unlike Graverson's and Heinzelman's testimony as to the meaning of "generic," Graverson testified that he does not think it is accurate to refer to HPP as a "generic equivalent" to Visbiome. ECF No. 56-4 at 41.

Brookfield's citation to the dictionary to support its definition of "generic" is inapposite under the framework suggested by its own case law; that is, a survey of the relevant industry players to ascertain the meaning of a term. *Steifel*, 2012 WL 12888436, at *9. However, Graverson, Heinzelman, and Kinsey, at a minimum, are industry players, and their proffered definitions of "generic" are sufficient to present a genuine dispute of material fact as to whether Brookfield's representations that HPP is a

"generic" of Visbiome are literally false.[13] *See Hot Wax, Inc. v. Turtle Wax, Inc.*, 27 F. Supp. 2d 1043, 1048 (N.D. Ill. 1998) (denying summary judgment on literal falsity because "[t]he parties have presented conflicting testimony and data regarding . . . the car wash industry's and consumer's understanding of the term 'wax', as well as the appropriate definition of the term wax"). The term "generic," given the evidence presented, is not so unambiguous that reasonable minds could not differ as to its meaning. And the Court cannot make credibility determinations between each party's proffered industry players' definitions of "generic." That task is left to the jury. The Court is therefore obliged to deny both parties' motions for summary judgment on the "generic" statements at this juncture given the genuine and material fact dispute. *See Schering-Plough Healthcare Prod., Inc. v. Schwarz Pharma, Inc.*, 547 F. Supp. 2d 939, 943–44 (E.D. Wis. 2008).

On the other hand, Brookfield does not cite any probiotics product or other industry players to support its definition of "generic equivalent." Given Brookfield's own testimony that it does not believe HPP can be considered a "generic equivalent" to Visbiome, combined with the evidence cited by ExeGi, however, the Court concludes that the use of the phrase "generic equivalent" *is* literally false. The undisputed evidence indicates that industry players view the term "generic equivalent" as meaning a "substitute" for or an "equivalent" to another product. Thus, the

[13] "[I]f a statement is literally true or ambiguous, a plaintiff must prove that the statement is misleading in context by demonstrated actual consumer confusion." *Schwarz Pharma*, 388 F. Supp. 2d at 977 (internal citations omitted). ExeGi does not substantively brief whether the "generic" statements are misleading. ECF No. 54 at 23. Therefore, the Court cannot continue the *Hot Wax* analysis as to the "generic" statements given the identified factual dispute.

undisputed evidence—particularly that products with different strains of bacteria within the same genus and species can have widely differing effects—makes it wholly clear to the Court that calling these products "generic equivalents" is literally false. ExeGi's false advertising Lanham Act claim as to the "generic equivalent" statements may proceed to the materiality step of the *Hot Wax* analysis.

4.1.4 Materiality of the "Same Probiotic Bacteria," "Same Strains," and "Generic Equivalent" Representations

At least five of the parties' ten submitted disputed facts address whether Brookfield's challenged statements actually influenced the drug compendia's, wholesalers', retailers', or ultimate consumers' decisions as to HPP compared to Visbiome. ECF No. 68 at 2. As this District recently observed, however, "[t]his argument implies that, to establish materiality, [the plaintiff] must prove that a specific commercial statement by [the defendant] actually affected a specific purchasing decision by a specific customer. Yet, in assessing materiality in this context, courts generally only require *a likely, as opposed to an actual, effect on consumer choice*." *e-ImageData Corp. v. Digit. Check Corp.*, No. 15-CV-658, 2018 WL 1411226, at *3 (E.D. Wis. Mar. 21, 2018) (emphasis added). Therefore, those disputed facts are immaterial. Factors that go to materiality of a representation include "(1) consumer motivation, which typically considers the importance of the product or service feature to which a misrepresentation is directed; (2) consumer reliance, which considers how a misrepresentation is used; and (3) consumer concern, which considers the extent to which a misrepresentation departs from the facts." Vincent N. Palladino, *Lanham Act "False Advertising" Claims: What Is A Plaintiff to Do?*, 101 Trademark Rep. 1601, 1626 (2011).

The Court finds the challenged statements material. As in *eImage*, the record shows that drug compendia had a set of "minimum requirements" to list products under the same GCN. *eImage*, 2018 WL 1411226, at *4. It is undisputed that Brookfield's marketing goal was to have HPP assigned to the same GCN as Visbiome and VSL #3. Brookfield also instructed its call center to field questions on the similarities between HPP and Visbiome or VSL #3 by using the word "same." The undisputed facts indicate that the targeted consumers were meant to hear the challenged statements prior to purchase. As to representations on the HDA form that HPP is a "generic equivalent" to Visbiome, Brookfield contends that the undisputed facts reveal that drug compendia relied only upon the labels of the products, and not the HDA form, in assigning GCNs. This fact is immaterial given the legal standard of *capacity* to influence choice, rather than actual influence. While evidence of actual influence is a factor, it is not dispositive.

ExeGi has submitted undisputed evidence—including emails from customers inquiring whether Visbiome is the "same" as HPP, ECF Nos. 56-11; 56-13; 56-18—that equivalence to Visbiome (or VSL #3) was "a product feature of concern to consumers." Palladino, 101 Trademark Rep. at 1630; *see also McNeilab, Inc. v. Am. Home Prods. Corp.*, 848 F.2d 34, 38 (2d Cir. 1988) ("A misleading comparison to a specific competing product necessarily diminishes that product's value in the minds of the consumer."). By representing that HPP is the "same" as Visbiome or a "generic equivalent" to Visbiome, Brookfield led customers to believe, among other things, that HPP, like Visbiome, has the De Simone Formulation, has been subject to over 70 human clinical trials, and has matching effects on the human body. The undisputed facts reveal that this is not the case. Based on this evidence

and the undisputed facts, no reasonable trier of fact could conclude that the statements were not material to consumers.

4.1.5 Actual Injury or Likelihood of Injury to ExeGi

The final factor in the *Hot Wax* test counsels that, "to succeed on a Lanham Act claim, [a] plaintiff must also demonstrate that it has been or is likely to be injured as a result of the false statement." *MillerCoors, LLC v. Anheuser-Busch Cos., LLC*, 385 F. Supp. 3d 730, 757 (W.D. Wis. 2019) (internal citations omitted). "The injury requirement can be satisfied by showing an injury to 'sales or business reputation.'" *Id.* (internal citations omitted). In analyzing injury, courts disfavor "conclusory testimony." *Id.*

In support of injury, ExeGi cites to expert reports and affidavits explaining generally that Brookfield's HPP has diverted sales from ExeGi's Visbiome, that ExeGi was initially unable to stock Visbiome at Costco, that ExeGi's goodwill was harmed, and that ExeGi has had to invest significant resources into corrective advertising. ECF No. 54 at 14–15, 22–23; ECF No. 63-1 at 5; ECF No. 62 at 3–4. ExeGi also cites customer statements explaining that the subject customers wanted to buy Visbiome but were sold HPP instead, including one customer who complained to ExeGi that a pharmacist informed her that HPP was the same as Visbiome and FDA-approved, both of which are (or the Court has determined to be) literally false. ECF Nos. 56-11; 56-13; 56-18. The undisputed facts further reveal that Brookfield wanted pharmacists to know that HPP is an available generic to VSL #3 or Visbiome as a lower cost alternative.

To prove actual injury or likelihood of injury, a plaintiff "[does] not need to establish [the defendant] charged lower prices to show it lost customers to [the defendant]." *Grove Fresh*, 969 F.2d at 558. The injury may instead be established through a showing that customers that would have

purchased from the plaintiff were lost to the defendant. *Id.* at 557. ExeGi has met this burden; specifically, ExeGi has demonstrated that it "would have made some, but not all, of [Brookfield's] sales but for [Brookfield's] misrepresentations." *BASF Corp. v. Old World Trading Co., Inc.*, 41 F.3d 1081, 1093 (7th Cir. 1994); *see also MillerCoors*, 385 F. Supp. 3d at 758 (consumer comments support a finding of reputational injury due to misleading advertisements).

ExeGi's customer emails indicate that at least some customers would have purchased Visbiome instead of HPP if Visbiome was available at their retailer(s), or if a pharmacist had sold them Visbiome. Brookfield's proffered evidence to dispute ExeGi's affidavits and expert reports on lost sales are, once again, testimony from drug compendia representatives explaining that they relied on the labels and not the HDA form in assigning GCNs. *See, e.g.*, ECF No. 68 at 2. The Court has already discussed this evidence ad nauseum and found it immaterial in the face of other undisputed facts, undisputed or not genuinely disputed evidence, and the applicable legal standards. ExeGi has met its burden as to the injury element, and is therefore entitled to summary judgment in its favor as to liability on its Lanham Act false advertising claim for the "same strains," "same probiotic bacteria," and "generic equivalents" statements.

4.2 ExeGi's Common Law Unfair Competition Claim

The parties agree that common law unfair competition claims are subject to the same legal standard as Lanham Act false advertising claims and arise from the same factual conduct subject to Lanham Act false advertising claims. ECF No. 49 at 31; ECF No. 54 at 32; *see also BenShot, LLC v. 2 Monkey Trading LLC*, No. 18-CV-1716, 2022 WL 1275604, at *6 (E.D. Wis. Apr. 8, 2022) (explaining, following analysis of Lanham Act false

advertising claim, the "Seventh Circuit's guidance that the same standard applies to both Wisconsin common law unfair competition claims and Lanham Act claims"). Accordingly, ExeGi is entitled to summary judgment in its favor as to liability on its common law unfair competition claim with regard to the "same strains," "same probiotic bacteria," and "generic equivalents" statements.

4.3 ExeGi's Common Law Tortious Interference with Contract Claim

Brookfield contends that ExeGi has not submitted any evidence supporting its claim that Brookfield interfered with ExeGi's prospective contract with the wholesaler McKesson. Under Wisconsin law, the elements of tortious interference with contract are "interference consist[ing] of (a) inducing or otherwise causing a third person not to enter into or continue the prospective relation or (b) preventing the other from acquiring or continuing the prospective relation." *Cudd v. Crownhart*, 364 N.W.2d 158, 160 (Wis. Ct. App. 1985).

In response, ExeGi submits that a genuine dispute of material fact exists because its Chief Executive Officer testified that, at the time VSL #3 left the market and Visbiome was poised to enter Costco through McKesson, Brookfield's claims that HPP was generic or a generic equivalent to Visbiome allowed HPP to enter the market through McKesson instead of Visbiome. ECF No. 82 at 27 (citing ECF No. 56-6 at 32). ExeGi also submits an email chain with McKesson in which McKesson informed ExeGi that it "found an alternative product solution, which [it is] currently distributing." ECF No. 86-6 at 3. At a minimum, this evidence presents a genuine and material dispute of fact on the claim. Therefore, Brookfield's motion for

summary judgment on ExeGi's tortious interference with contract claim will be denied.

4.4 Permanent Injunctive Relief

ExeGi moves for permanent injunctive relief on its claims for false advertising under the Lanham Act, common law unfair competition, and for fraudulent representation under Section 100.18. ECF No. 54 at 34. The Court analyzes the request as to the first two claims for the reasons stated above. *See supra* note 9.

"Permanent injunctive relief is appropriate when a plaintiff has shown: (1) success . . . on the merits; (2) irreparable harm; (3) that the benefits of granting the injunction outweigh the injury to the defendant; and, (4) that the public interest will not be harmed by the relief requested." *Lacy v. Cook County, Ill.*, 897 F.3d 847, 867 (7th Cir. 2018); *see also SunFrog*, 311 F. Supp. 3d at 1049 (same as applied to Lanham Act case).

The Court has already determined that ExeGi has shown success on the merits of its Lanham Act false advertising and common law unfair competition claims as to the "same strains," "same probiotic bacteria," and "generic equivalents" statements.

As to the second element for permanent injunctive relief, the Seventh Circuit recognizes the "well-established presumption that injuries arising from Lanham Act violations are irreparable, even absent a showing of business loss." *Abbott Labs.*, 971 F.2d at 16. In support of its argument that irreparable harm should not be presumed, Brookfield argues only that ExeGi is unable to prove that any of its challenged statements are literally false. ECF No. 88 at 25. The Court has already determined the contrary. Brookfield also pleads the Court not to allow ExeGi a monopoly on high potency probiotic products. However, the scope of ExeGi's proposed

permanent injunction would not remove HPP from the market; it would address only cessation of the challenged statements. ECF No. 53-1. The Court will further limit ExeGi's proposed permanent injunction to conform with the Court's holdings in this Order, as well as limit ExeGi's proposed permanent injunction to only challenged statements that the parties substantively briefed. In other words, the injunction will not address any medical food claims on labeling or otherwise, any claims that HPP is a "generic" of Visbiome, or any other challenged statements that were not substantively briefed in the parties' cross-motions for summary judgment.

This conclusion aligns with Seventh Circuit case law. For example, in *Abbott Laboratories*, the Seventh Circuit reversed the district court after the district court concluded that the presumption of irreparable harm was rebutted where it assumed that an injunction would ultimately remove the competing product from the market. 971 F.2d at 16. The Seventh Circuit explained that "the district court erred by assuming in the first instance that granting final injunctive relief to Abbott would necessarily mean the end of Ricelyte." *Id.* at 17. Rather, the relief sought by the Abbott—"e.g., an order prohibiting Mead from purveying the false 'rice claims' and directing it to issue corrective advertisements and brochures—would not have such drastic consequences." *Id*.

As in *Abbott Laboratories*, the equities here are appropriately balanced. The injunction will address the Lanham Act violations the Court has adjudicated, while preserving HPP's presence in the market. Other than the two arguments discussed above, namely that the presumption of irreparable harm is rebutted and ExeGi should not be entitled to a monopoly, Brookfield does not brief the permanent injunction factors; therefore, it waives those issues. *SunFrog*, 311 F. Supp. 3d at 1010. The Court

finally determines that the public's interest will be served by eliminating customer confusion in the marketplace. *See Promatek Indus., Ltd. v. Equitrac Corp.*, 300 F.3d 808, 813–14 (7th Cir. 2002). Therefore, ExeGi's request for permanent injunctive relief will be granted. The permanent injunction, as modified, will be issued as a separate order entered contemporaneously with this Order.

5. CONCLUSION

Based on the foregoing, the Court has concluded that (1) all of the disputed statements are commercial advertisements or promotions; (2) Brookfield is entitled to summary judgment in its favor that a determination of literal falsity of any "medical foods" claims is precluded by the FDCA, and accordingly any Lanham Act claim as to the "medical foods" representations is dismissed without prejudice; (3) ExeGi's Section 100.18 claim is dismissed without prejudice; (4) ExeGi is entitled to summary judgment in its favor as to liability on its Lanham Act false advertising and common law unfair competition claims with regard to the "same probiotic bacteria," "same strains," and "generic equivalent" statements, and a permanent injunction will be entered accordingly by separate order; (5) genuine disputes of material fact exist as to ExeGi's Lanham Act false advertising and common law unfair competition claims with regard to the "generic" statements; and (6) Brookfield's motion for summary judgment on ExeGi's Lanham Act unfair competition and common law tortious interference with contract claims is denied.

Accordingly,

IT IS ORDERED that Plaintiff ExeGi Parma LLC's motion for partial summary judgment, ECF No. 53, be and the same is hereby **GRANTED in part and DENIED in part**;

IT IS FURTHER ORDERED that Defendant Brookfield Pharmaceuticals, LLC's motion for summary judgment, ECF No. 48, be and the same is hereby **GRANTED in part and DENIED in part**;

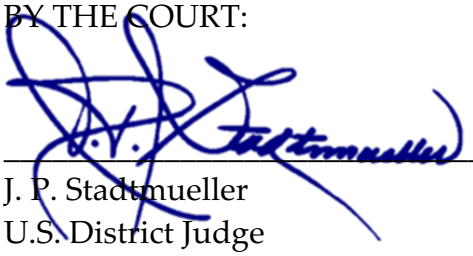
IT IS FURTHER ORDERED that the parties' motions to seal and/or restrict, ECF Nos. 47, 52, 72, 78, 81, 89, 90, 91, 96, be and the same are hereby **GRANTED**; the Clerk of Court is **DIRECTED** to maintain the documents subject to the motions under seal and/or in restricted form;

IT IS FURTHER ORDERED that Plaintiff ExeGi Pharma LLC's claim for fraudulent representation in violation of Wis. Stat. § 100.18, as well as any claim under the Lanham Act, 15 U.S.C. § 1125(a), regarding "medical food" representations, be and the same are hereby **DISMISSED without prejudice**; and

IT IS FURTHER ORDERED that Plaintiff ExeGi Pharma LLC is entitled to summary judgment in its favor as to liability on its Lanham Act false advertising and common law unfair competition claims with regard to the "same probiotic bacteria," "same strains," and "generic equivalent" statements, and permanent injunctive relief will be entered by separate order as set forth in the body of this Order.

Dated at Milwaukee, Wisconsin, this 21st day of March, 2023.

BY THE COURT:



J. P. Stadtmueller
U.S. District Judge