IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MARYLAND, NORTHERN DIVISION

BNLFOOD INVESTMENTS LIMITED SARL,	*	
Plaintiff,	*	
v.	*	CIVIL NO.: WDQ-11-0446
MARTEK BIOSCIENCES CORP.,	*	
Defendants.	*	

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MEMORANDUM OPINION

BNLfood Investments Limited SARL ("BNLfood") sued Martek Biosciences Corporation ("Martek") for violations of Section 2 of the Sherman Act,[1] Section 3 of the Clayton Act,[2] and the Maryland Antitrust Act.[3] For the following reasons, Martek's motion to dismiss the amended complaint will be denied.[4]

I. Background[5]

BNLfood is a group of international companies based in Luxembourg that has produced and marketed eggs, egg-derived

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[1] 15 U.S.C. § 2.

[2] 15 U.S.C. § 14.

[3] Md. Code Ann., Com. Law §§ 11-201 *et seq.*

[4] Martek's motion to dismiss the original complaint (ECF No. 4) will be denied as moot.

[5] For Martek's motion to dismiss, the well-pled allegations in BNLfood's amended complaint are accepted as true. *See Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993).

ingredients and additives, and egg-extracted proteins for 40 years. Am. Compl. ¶ 12-13. Its ingredients are distributed in more than 60 countries worldwide. *Id.*

Martek is a Delaware corporation with its principal place of business in Columbia, Maryland. Am. Compl. ¶ 15. Martek makes food ingredients from algae and fungi, including Omega-3 docosahexaenoic acid ("DHA")[6] and Omega-6 arachidonic acid ("ARA").[7] *Id.* Its DHA product, *life'sDHA*, is the only source of DHA used in infant formula in the United States and is used in more than 99 percent of all formula in the U.S. market. Am. Compl. ¶ 17. Martek holds the patent for bioengineered ARA. Am. Compl. ¶ 20.

Martek uses "long-term, sole-source contracts" that "punish" infant formula producers that do not buy DHA and ARA exclusively from Martek. Am. Compl. ¶ 5. Manufacturers that deal exclusively with Martek receive "substantial price reductions." Am. Compl. ¶ 36.

In 1996, BNLfood began developing egg-phospholipids ("PPLs")[8] composed mainly of DHA and ARA made from eggs. Am.

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[6] DHA is used in infant formula, pregnancy and nursing products, foods, beverages, dietary supplements, and animal feeds. Am. Compl. ¶ 16.

[7] ARA is used in infant formula and baby milk. Am. Compl. ¶ 16.

[8] Phospholipids are organic compounds of fats and other similar substances that are found in cell membranes. *Websters New World*

Compl. ¶ 13, 38. In 2002, BNLfood notified the Food and Drug Administration ("FDA") of its intent to market its PPLs for use in food. *Id.* Today BNLfood's PPLs are sold as toddler food supplements in the United States. *Id.*

BNLfood markets and sells its DHA and ARA in Europe and Asia but also wants to sell the ingredients in the United States. Am. Compl. ¶ 14. BNLfood is preparing to notify the FDA that its ingredients are "generally recognized as safe" ("GRAS"). *Id.* Under the Food, Drug, and Cosmetic Act,[9] any substance intentionally added to food is a food additive subject to premarket FDA approval, unless the substance is GRAS. 21 U.S.C. §§ 321(s), 348(b). Although the FDA need not formally declare a substance GRAS, a manufacturer may ask the FDA to decide whether "a sufficient basis" exists for the manufacturer's GRAS determination.[10] Infant formula manufacturers in the United States generally purchase ingredients that are GRAS. Am. Compl. ¶ 47.

Dictionary 788, 1016 (3d college ed. 1988).

[9] 21 U.S.C. §§ 301, *et seq.*

[10] FDA, *Guidance for Industry: Frequently Asked Questions about GRAS* (December 2004) [hereinafter "*FAQs About GRAS*"], *available at www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/*; Proposed Rule: Substances Generally Recognized As Safe, 62 Fed. Reg. 18,938, 18,950 (Apr. 17, 1997).

To participate in the FDA's voluntary GRAS "notification program," a manufacturer provides the agency a notice describing the substance, the conditions of its use, and the scientific procedures the manufacturer used to conclude that the substance is GRAS.[11] *FAQs About GRAS*. The FDA aims to complete each review within 180 days. *Id.* BNLfood estimates that its FDA review will take about 180 days. Am. Compl. ¶ 14.

In addition to preparing its GRAS notice to the FDA, BNLfood has made "significant" expenditures on research, development and marketing, and spent more than €10 million building and expanding its facilities to market DHA and ARA to U.S. infant formula manufacturers. Am. Compl. ¶¶ 45-46.

BNLfood has also tried to deal with major infant formula manufacturers in the United States. Am. Compl. ¶ 4. Some manufacturers have placed orders with BNLfood or have tested its products. Am. Compl. ¶ 45. Other potential customers have said they are interested in dealing but are prohibited by their long-term contracts with Martek. Am. Compl. ¶ 6.

On February 17, 2011, BNLfood sued, alleging that Martek's long-term sole-source contracts violate (1) Section 2 of the Sherman Act by lessening competition or tending to create or maintain a monopoly in the U.S. market, and (2) Section 3 of the

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[11] BNLfood has hired experts and compiled a "dossier of scientific data" for its notice. Am. Compl. ¶ 46.

Clayton Act, and the Maryland Antitrust Act, by unreasonably restraining trade in the U.S. market. Comp. ¶ 50. On April 18, 2011, Martek moved to dismiss. ECF No. 4. On May 5, 2011, BNLfood amended its complaint. ECF No. 12.[12] On May 23, 2011, Martek moved to dismiss the amended complaint. ECF No. 19.

II. Analysis

A. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), an action may be dismissed for failure to state a claim upon which relief can be granted. A Rule 12(b)(6) motion tests the legal sufficiency of a complaint, but does not "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *Presley v. City of Charlottesville*, 464 F.3d 480, 483 (4th Cir. 2006).

The Court bears in mind that Rule 8(a)(2) requires only a "short and plain statement of the claim showing that the pleader is entitled to relief." *Migdal v. Rowe Price-Fleming Int'l, Inc.*, 248 F.3d 321, 325-26 (4th Cir. 2001).

Although Rule 8's notice-pleading requirements are "not onerous," the plaintiff must allege facts that support each element of the claim advanced. *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 764-65 (4th Cir. 2003). These facts must be

[12] BNLfood also opposed Martek's motion to dismiss the original complaint. ECF No. 13.

sufficient to "state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007).

To present a facially plausible complaint, a plaintiff must do more than "plead[] facts that are 'merely consistent with' a defendant's liability"; the facts as pled must "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (*quoting Twombly*, 550 U.S. at 557). The complaint must not only allege but also "show" that the plaintiff is entitled to relief. *Id.* at 1950 (*quoting* Fed. R. Civ. P. 8(a)(2)).

"[W]he[n] the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged--but it has not show[n]--that the pleader is entitled to relief." *Id.* (citation and internal quotation marks omitted).

The Court "should view the complaint in a light most favorable to the plaintiff," and "accept as true all well-pleaded allegations," *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993), but the Court is "not bound to accept as true a legal conclusion couched as a factual allegation," *Papasan v. Allain*, 478 U.S. 265, 286 (1986), or "allegations that are mere[] conclus[ions], unwarranted deductions of fact, or

unreasonable inferences," *Veney v. Wyche*, 293 F.3d 726, 730 (4th Cir. 2002) (citation and internal quotation marks omitted).

B. Martek's Motion to Dismiss

BNLfood asserts that Martek's long-term sole-source contracts violate (1) Section 2 of the Sherman Act by lessening competition or tending to create or maintain a monopoly in the U.S. market, and (2) Section 3 of the Clayton Act, and the Maryland Antitrust Act, by unreasonably restraining trade in the U.S. market. Am. Comp. ¶ 52. It seeks treble damages and injunctive relief. Am. Comp. ¶ 18. Martek contends that BNLfood lacks standing to sue because it has alleged neither an "antitrust injury" (required for standing to bring an antitrust action) nor actual injury (required for standing to bring any federal action under Article III of the Constitution). ECF No. 19 at 21, 30.

1. Antitrust Injury

"In a private antitrust action, a plaintiff must go beyond a showing that it meets the Article III standing requirements of injury, causation, and redressability; it must also demonstrate 'antitrust standing.'" *Novell, Inc. v. Microsoft Corp.*, 505 F.3d 302, 310 (4th Cir. 2007). In deciding whether a plaintiff has antitrust standing, a court must consider five factors:

> (1) the causal connection between an antitrust violation and harm to the plaintiffs, and whether that harm was intended; (2) whether the harm was of a type

> that Congress sought to redress in providing a private remedy for violations of the antitrust laws; (3) the directness of the alleged injury; (4) the existence of more direct victims of the alleged antitrust injury; and (5) problems of identifying damages and apportioning them among those directly and indirectly harmed.

Id. at 311. The first two factors encompass "antitrust injury"; they "ensure that the plaintiff claims the proper *type* of injury." *Id.* at 311, 315. The other three factors, which weigh the "directness or remoteness of the plaintiff's alleged antitrust injury," may "further constrict the number of private plaintiffs" who may sue. *Id.*

The antitrust laws protect not only consumers and competitors, but all victims of prohibited practices. *See Mandeville Island Farms, Inc. v. Am. Crystal Sugar Co.*, 334 U.S. 219, 236 (1948). Thus, a defendant's potential competitor may bring an antitrust action if it can show genuine intent and preparedness to enter the relevant market.[13] A plaintiff may show this through its background and experience in the field, financial ability to enter the market, relevant contracts, and

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[13] *See, e.g., Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 807 (D.C. Cir. 2001); *Gas Utils. Co. of Ala., Inc. v. S. Natural Gas Co.*, 996 F.2d 282, 283 (11th Cir. 1993) (per curiam); *Bupar v. Ampco Foods, Inc.*, 752 F.2d 445, 450 (9th Cir. 1985); *Grip-Pak, Inc. v. Ill. Tool Works, Inc.*, 694 F.2d 466, 475 (7th Cir. 1983); *Huron Valley Hosp., Inc. v. City of Pontiac*, 666 F.2d 1029, 1033 (6th Cir. 1981); *Martin v. Phillips Petroleum Co.*, 365 F.2d 629, 633 (5th Cir. 1966).

acquisition of necessary facilities and equipment.[14]

Martek argues that BNLfood lacks antitrust standing because it has not shown its intent and preparedness to enter the U.S. DHA/ARA market. ECF No. 19 at 23. Martek contends that a mere plan to file a GRAS notice does not show the requisite preparedness, because FDA GRAS reviews can take many years.[15] Martek also argues that BNLfood has failed to consider how long it will take infant formula manufacturers using its ingredients to comply with the requirements of the Infant Formula Act.[16]

BNLfood counters that it has alleged several indicia of its intent and preparedness to enter the U.S. DHA/ARA market: its 40

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[14] *Bupar*, 752 F.2d at 452; *Curtis v. Campbell-Taggart, Inc.*, 687 F.2d 336, 338 (10th Cir. 1982); *Huron Valley Hosp., Inc.*, 666 F.2d at 1033; *Hecht v. Pro-Football, Inc.*, 570 F.2d 982, 994 (D.C. Cir. 1977).

[15] Martek cites two examples of FDA GRAS reviews of DHA and ARA that took more than 180 days: (1) a 52-month review of Abbott Laboratories' notice; and (2) a 14-month review of Martek's notice, after the FDA rejected a notice filed 18 months earlier. ECF No. 19 at 17-18, *citing* FDA Agency Response Letters/GRAS Notices Nos. 000041 (May 17, 2001), 000007 (Mar. 4, 1999), and 000094 (Apr. 18, 2006), *available at www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing* (click on "GRAS Database Listing," sort by "GRN No. ASC," then click on records 7, 41 and 94) (last visited Dec. 6, 2011).

[16] ECF No. 19 at 25-27. Infant formula manufacturers must notify the FDA 90 days before marketing any formula that has undergone a "major change" in "processing or formulation," such as the use of new ingredients. 21 U.S.C. § 350a(d); 21 C.F.R. § 106.30(c)(2). Martek contends that this process "could add years" to BNLfood's anticipated entry to the U.S. market, because the formula manufacturers will have to conduct "clinical testing" to ensure the safety of the formula. ECF No. 19 at 26; ECF No. 21 at 6.

years of experience producing and marketing egg-derived food additives in 60 countries; its development of PPLs composed of DHA and ARA; European Union approval for its PPLs; its 2002 notification to the FDA that it intended to market PPLs for use in food; current use of its PPLs in toddler food supplements in the United States; the more than €10 million it has spent to build and expand its facilities to manufacture DHA and ARA for U.S. customers; its contracts for staff and equipment to enter the U.S. market; the sale of its PPLs to infant formula manufacturers outside the United States; the marketing of its ingredients to U.S. customers; its contacts with potential U.S. customers, who have said they cannot deal with BNLfood because of Martek's contracts; and its pursuit of FDA review of its GRAS determination. ECF No. 20 at 4-5. BNLfood also contends that the Infant Formula Act does not apply to it, because BNLfood does not manufacture infant formula. ECF No. 20 at 12.

BNLfood has adequately pled the intent and preparedness necessary to establish antitrust standing. It alleges facts demonstrating experience in the field, financial ability to enter the market, relevant contracts, and acquisition of equipment, facilities, and staff. *See e.g.*, *Hecht*, 570 F.2d at 994. FDA review of BNLfood's GRAS determination is voluntary, and alleging mere anticipation of FDA approval may indicate

preparedness to enter a market.[17] At this stage, BNLfood need not address a statute (the Infant Formula Act) that does not bind manufacturers of individual ingredients of formula. *See supra* n.16. Martek's list of other reasons for BNLfood's failure to enter the market does not require dismissal of the complaint. "[A]t the motion to dismiss stage" of an antitrust action, "the plaintiff's allegations need not rule out a defendant's explanations." *Haley Paint Co. v. E.I. Dupont de Nemours & Co.*, ---F. Supp. 2d---, 2011 WL 1197643, at *5 (D Md. 2011). Rather, the plaintiff must simply allege "plausible grounds" for its claim -- "enough facts to raise a reasonable expectation that discovery will reveal evidence" of the claim. *See Twombley*, 550 U.S. at 556.[18]

BNLfood has sufficiently pled antitrust injury by asserting that it has been "excluded from participat[ing] in a particular market, and the result [is] a decrease in competition in that market." *E.I. Dupont de Nemours & Co. v. Kolon Indus., Inc.*, 688 F. Supp. 2d 443, 460 (E.D. Va. 2009) (internal citations and

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[17] *See Andrx Pharma. Inc.*, 256 F.3d at 807-08; *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, Case No. 09-CV-1638, 2010 WL 331704, at *3 (E.D. Pa. Jan. 26, 2010) ("the *Andrx* court does not declare that a specific allegation regarding probability of FDA approval is an absolute requirement of the intent and preparedness standard").

[18] "[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Twombley*, 550 U.S. at 556.

quotation marks omitted). "Beyond that, an analysis of antitrust injury is more properly conducted after discovery." *Id.* (internal citation and quotation marks omitted).

2. Actual Injury

Martek also argues that BNLfood has failed to allege an injury in fact entitling it to damages under Article III, or irreparable harm entitling it to injunctive relief. *See* ECF No. 19 at 30-31; ECF No. 21 at 9.

Article III standing requires plaintiffs to show, *inter alia*, "an injury in fact that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Lux v. Judd*, 651 F.3d 396, 400 (4th Cir. 2011). "The concept of antitrust standing is narrower than constitutional standing." *Novell*, 505 F.3d at 311 n.16. Thus, "[h]arm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact." *Associated Gen. Contractors of Calif., Inc. v. Calif. State Council of Carpenters*, 459 U.S. 519, 535 n.31 (1983). Because BNLfood adequately alleged antitrust injury, *see supra* Part II.B.1, it has adequately pled an Article III injury.

To obtain injunctive relief, a plaintiff generally must prove, *inter alia*, irreparable injury. *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 126 (4th Cir. 2011). But "where a statute authorizes injunctive relief for its enforcement,

plaintiffs need not plead and prove irreparable injury." *Envtl. Def. Fund, Inc. v. Lamphier*, 714 F.2d 331, 338. BNLfood seeks injunctive relief under Section 16 of the Clayton Act, which states that a plaintiff "shall be entitled to . . . have injunctive relief . . . against threatened loss or damage by a violation of the antitrust laws." 15 U.S.C. § 26. Accordingly, BNLfood need not plead irreparable injury.

III. Conclusion

For the reasons stated above, Martek's motion to dismiss the amended complaint will be denied.

12/13/11
Date

William D. Quarles, Jr.
United States District Judge