Slip Op. 23-170

UNITED STATES COURT OF INTERNATIONAL TRADE

NUTRICIA NORTH AMERICA, INC., Plaintiff, v. **UNITED STATES,** Defendant.	**Before: Timothy C. Stanceu, Judge** **Court No. 16-00008**

OPINION

[Granting defendant's cross-motion for summary judgment on the tariff classifications of various nutritional preparations intended for use by patients with medical conditions]

Dated: December 4, 2023

John B. Brew, Crowell & Moring LLP, of Washington, D.C., for plaintiff. With him on the briefs was *Alexander H. Schaefer*. Also on the briefs were *Maria T. Vanikiotis* and *Alexander T. Rosen*, Crowell & Moring LLP, of New York, N.Y.

Luke Mathers, Trial Attorney, Commercial Litigation Branch, Civil Division, U.S. Department of Justice, of New York, N.Y., for defendant. With him on the briefs were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, *Patricia M. McCarthy*, Director, *Justin R. Miller*, Attorney-In-Charge, and *Aimee Lee*, Assistant Director, Commercial Litigation Branch. Of counsel on the briefs was *Yelena Slepak*, Office of the Assistant Chief Counsel for International Trade Litigation, U.S. Customs and Border Protection.

Stanceu, Judge: Plaintiff Nutricia North America, Inc. ("Nutricia"), contesting the denials by U.S. Customs and Border Protection ("Customs" or "CBP") of its administrative protests, claims that Customs incorrectly determined the tariff

classification of five imported products it describes as "medical foods." Before the court are the parties' cross-motions for summary judgment. The court awards summary judgment in favor of defendant United States.

I. BACKGROUND

The merchandise was imported on four entries made in November 2014 at the ports of Philadelphia, Pennsylvania and Washington-Dulles. Upon CBP's denial of its protests of the liquidations of these entries, plaintiff commenced this action. Summons (Jan. 8, 2016), ECF No. 1.

Plaintiff moved for summary judgment, arguing for tariff classification in either of two duty-free tariff classifications. Pl.'s Mot. for Summary J. (Aug. 31, 2022), ECF Nos. 73 (Conf.), 74 (Public); Mem. of Law and Authorities in Supp. of Pl.'s Mot. for Summary J. (Aug. 31, 2022), ECF Nos. 73 (Conf.), 74 (Public) ("Pl.'s Br."). Defendant responded and cross-moved for summary judgment, maintaining that the tariff classification determined by Customs upon liquidation of the entries was correct. Def.'s Cross-Mot. for Summary J. and Resp. in Opp'n to Pl.'s Mot. for Summary J. (Oct. 28, 2022), ECF Nos. 80 (Conf.), 81 (Public); Def.'s Mem. in Supp. of its Cross-Mot. for Summary J. and Resp. in Opp'n to Pl.'s Mot. for Summary J. (Oct. 28, 2022), ECF Nos. 80 (Conf.), 81 (Public) ("Def.'s Br.").

II. DISCUSSION

A. Jurisdiction and Standard of Review

The court exercises jurisdiction according to Section 201 of the Customs Courts Act of 1980, 28 U.S.C. § 1581(a)[1], which grants the court "exclusive jurisdiction of any civil action commenced to contest the denial of a protest, in whole or in part, under section 515" of the Tariff Act of 1930 ("Tariff Act"), *as amended*, 19 U.S.C. § 1515. The court adjudicates *de novo* actions to contest the denial of a protest. 28 U.S.C. § 2640(a)(1) ("The Court of International Trade shall make its determinations upon the basis of the record made before the court.").

The 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." USCIT R. 56(a). In a tariff classification dispute, summary judgment is appropriate where "there is no genuine dispute as to the nature of the merchandise and the classification determination turns on the proper meaning and scope of the relevant tariff provisions." *Deckers Outdoor Corp. v. United States*, 714 F.3d 1363, 1371 (Fed. Cir. 2013) (citations omitted).

[1] All citations herein to the United States Code are to the 2012 edition.

B. Description of the Merchandise

The facts stated in this Opinion to describe the imported merchandise are taken from the submissions of the parties in support of their respective summary judgment motions and are not in dispute between the parties. From a review of these submissions, the court concludes that there is no genuine dispute as to the facts material to the classification of the products at issue.

The five imported products at issue in this case are "MSUD Lophlex® LQ," "Periflex® Infant," "Periflex® Junior," "Neocate® Junior," and "Ketocal® Liquid." Plaintiff describes the five imported products as "certain Medical Foods, which are a unique class of products defined and regulated by the Food and Drug Administration ('FDA') under the Orphan Drug Act, 21 U.S.C. § 360ee." Pl.'s Br. 1. Plaintiff further describes these products as "Medical Foods that are specially designed, produced and intended for use by infants or toddlers who suffer from a variety of diseases or disorders." *Id*. (citations omitted). All five products are labeled as having been manufactured in Liverpool, United Kingdom. *Id*. at Exs. 20A–20E.

MSUD Lophlex® LQ "is used as nutrition therapy for children who suffer from a severe, life threatening, and permanent disorder called branched-chain alpha ketoacid dehydrogenase complex (BCKDC) deficiency, (also called Maple Syrup Urine Disease or MSUD), an inborn error of the metabolism" that causes "impaired ability to

metabolize three of the twenty essential amino acids: leucine, valine and isoleucine." *Id*. at 6–7 (citations omitted).

Periflex® Infant and Periflex® Junior are produced for use by patients with Phenylketonuria (PKU), which is an "inborn error of metabolism of phenylalanine" that is "characterized by inadequate formation of L-tyrosine, elevation of serum L-phenylalanine, urinary excretion of phenylpyruvic acid and other derivatives, and accumulation of phenylalanine and its metabolites." *Id*. at 8 (citation omitted). The condition "can produce brain damage resulting in severe mental retardation, often with seizures, other neurologic abnormalities such as retarded myelination and deficient melanin formation leading to hypopigmentation of the skin and eczema." *Id*. (citation omitted).

Neocate® Junior is produced for use by patients who suffer from Eosinophilic Esophagitis (EoE), which is "an immune-mediated disease of the esophagus," *id.* at 10 (citation omitted), Short Bowel Syndrome (SBS), which "may occur when those portions of the small intestine have been removed or when portions of the small intestine are missing or damaged at birth," *id*. at 11 (citation omitted), and other diseases and disorders, *id*. at 10 (citations omitted).

Ketocal® Liquid is produced for use by patients who suffer from Intractable/Refractory Epilepsy, Glucose Transporter Type 1 Deficiency (GLUT 1), and other diseases and disorders. *Id*. at 12–13. GLUT 1 "is a lifelong genetic metabolic

disorder that occurs as a result of mutation in the SLC2A1 gene." *Id*. at 13 (citation omitted). "Persons with GLUT 1 demonstrate epilepsy, developmental delays, acquired microcephaly, cognitive impairment and varying degrees of spasticity, ataxia, and dystonia." *Id*. (citation omitted).

C. Tariff Classification under the HTSUS

Tariff classification under the Harmonized Tariff Schedule of the United States ("HTSUS") is governed by the General Rules of Interpretation ("GRIs") and, if applicable, the Additional U.S. Rules of Interpretation ("ARIs"), both of which are contained in the statutory text of the HTSUS. *Dependable Packaging Solutions, Inc. v. United States,* 757 F.3d 1374, 1377 (Fed. Cir. 2014) (citations omitted) ("Along with the headings and subheadings . . . the HTSUS statute also contains the 'General Notes,' the 'General Rules of Interpretation' ('GRI'), the 'Additional United States Rules of Interpretation' ('ARI'), and various appendices for particular categories of goods.").

The GRIs are applied in numerical order, with GRI 1 providing, in pertinent part, that "classification shall be determined according to the terms of the headings and any relative section or chapter notes." GRI 1, HTSUS. GRIs 2 through 5 apply "provided such headings or notes do not otherwise require." *Id.*

After determining the correct four-digit heading, the court determines the correct subheading by applying GRI 6, HTSUS (directing determination of the subheading

"according to the terms of those subheadings and any related subheading notes and, mutatis mutandis, to the above rules" [GRIs 1 through 5]).

D. Judicial Review in Tariff Classification Disputes

In adjudicating a tariff classification dispute, the court first considers whether "the government's classification is correct, both independently and in comparison with the importer's alternative." *Jarvis Clark Co. v. United States*, 733 F.2d 873, 878 (Fed. Cir. 1984) ("*Jarvis Clark*"). The plaintiff has the burden of showing that the government's classification of the subject merchandise was incorrect. *Id.*, 733 F.2d at 876. Subject to the plaintiff's rebuttal, factual determinations by Customs are presumed correct, *see* 28 U.S.C. § 2639(a)(1), but the presumption of correctness applies to issues of fact and not questions of law, *Goodman Mfg. L.P. v. United States,* 69 F.3d 505, 508 (Fed. Cir. 1995). If the plaintiff satisfies its burden of demonstrating that the government's classification was incorrect, the court must ascertain "the *correct* result, by whatever procedure is best suited to the case at hand." *Jarvis Clark*, 733 F.2d at 878 (footnote omitted).

In determining the correct classification, the court undertakes a two-step analysis. *Faus Grp., Inc. v. United States,* 581 F.3d 1369, 1371 (Fed. Cir. 2009). "The first step addresses the proper meaning of the relevant tariff provisions, which is a question of law." *Id.* (citation omitted). "The second step involves determining whether the merchandise at issue falls within a particular tariff provision as construed, which, when disputed, is a question of fact." *Id*. at 1371–72 (citation omitted).

"Absent contrary legislative intent, HTSUS terms are to be construed according to their common and commercial meanings." *La Crosse Tech., Ltd. v. United States*, 723 F.3d 1353, 1358 (Fed. Cir. 2013) (quoting *Carl Zeiss, Inc. v. United States*, 195 F.3d 1375, 1379 (Fed. Cir. 1999)). When interpreting tariff terms in the HTSUS, the court "may consult lexicographic and scientific authorities, dictionaries, and other reliable information sources." *Carl Zeiss*, 195 F.3d at 1379 (citing *Baxter Healthcare Corp. of P.R. v. United States*, 182 F.3d 1333, 1337 (Fed. Cir. 1999)).

The court also consults the Explanatory Notes ("ENs") for the Harmonized Commodity Description and Coding System ("Harmonized System" or "HS") maintained by the World Customs Organization. Although not legally binding, the Explanatory Notes "are generally indicative of the proper interpretation of a tariff provision." *Degussa Corp. v. United States*, 508 F.3d 1044, 1047 (Fed. Cir. 2007) (citing *Motorola, Inc. v. United States*, 436 F.3d 1357, 1361 (Fed. Cir. 2006)). The HTSUS is organized according to Harmonized System rules and nomenclature (pursuant to the "Harmonized System Convention"). The Explanatory Notes are informative as to the intent of the drafters of the Harmonized System where, as in this case, the dispute involves a legal determination of the scope of the competing headings as determined under the GRIs.

E. Claims of the Parties

Upon liquidation, Customs classified Nutricia's imported products in subheading 2106.90.9998, HTSUS[2] ("Food preparations not elsewhere specified or included: Other: Other: Other: Other: Other: Other: Other: Other: Other: Other"), subject to duty at 6.4% *ad valorem*. Defendant maintains that this classification determination is correct.

Plaintiff claims classification of the products in subheading 3004.50.5040, HTSUS ("Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale: Other medicaments containing vitamins or other products of heading 2936: Other: Other: Other"), free of duty.

In the alternative, plaintiff claims classification of the products in a special U.S. duty-free tariff classification provision within chapter 98, HTSUS, specifically, subheading 9817.00.96 ("Articles specially designed or adapted for the use or benefit of the blind or other physically or mentally handicapped persons; parts and accessories (except parts and accessories of braces and artificial limb prosthetics) that are specially designed or adapted for use in the foregoing articles: . . . Other").

---

[2] The products at issue were subject to the tariff provisions set forth in the version of the Harmonized Tariff Schedule of the United States ("HTSUS") that was in effect on the dates of entry. References to the HTSUS herein are to the 2014 version.

The court first determines the correct classification of the five products according to the GRIs and the tariff provisions in chapters 1 through 97, HTSUS. It then addresses the issue of whether these products qualify for the special classification provision plaintiff claims in the alternative.

F. Application of GRI 1, HTSUS, to Determine the Appropriate Heading

As required by GRI 1, HTSUS, the court first considers the terms of the headings and any relative section and chapter notes in ascertaining the correct four-digit heading for the classification of the imported products. The parties have identified the following candidate headings:

Heading 2106, HTSUS:	"Food preparations not elsewhere specified or included"
Heading 3004, HTSUS:	"Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale"

The parties have not advocated, and the court has not identified, any other candidate headings within chapters 1 through 97, HTSUS.

1. Classification under Heading 3004 Is Precluded by Note 1(a) to Chapter 30

The terms of headings 3003 and 3004 are in parallel and similar in description, except that heading 3003 is limited to mixed products "*not* put up in measured doses or in forms or packings for retail sale," as follows:

> Heading 3003, HTSUS: "Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, *not* put up in measured doses or in forms or packings for retail sale"

Heading 3003, HTSUS (emphasis added). Thus, the products of heading 3004, unless unmixed, would be classified under heading 3003 if imported in bulk form. Although the HTSUS does not define the heading term "medicament," the Explanatory Note to HS heading 30.03 states, in language equally applicable to heading 30.04, that "[t]his heading covers *medicinal preparations* for use in the internal or external treatment or prevention of human or animal ailments."[3] EN 30.03 (2014) (emphasis added).[4]

It could be argued that the products under consideration are medicaments because they are "for use in the internal . . . treatment . . . of human . . . ailments." *Id*.

---

[3] Similarly, dictionaries consider the term "medicament" synonymous with terms such as "medicinal substance" and "medication." As defendant points out, Webster's Third New International Dictionary and the Merriam-Webster Online Dictionary define "medication" as "a medicinal substance: MEDICAMENT." Def.'s Mem. in Supp. of its Cross-Mot. for Summary J. and Resp. in Opp'n to Pl.'s Mot. for Summary J. 14 (Oct. 28, 2022), ECFs No. 80 (Conf.), 81 (Public); *Medication*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY UNABRIDGED (2002); *Medication*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/medication (last visited Dec. 4, 2023). The Oxford English Dictionary defines "medicament" as "a *substance used for medical treatment*; a medicine, remedy." *Medicament*, OXFORD ENGLISH DICTIONARY, https://www.oed.com/dictionary/medicament_n?tab=meaning_and_use#37536447 (last visited Dec. 4, 2023) (emphasis added).

[4] Citations to the Explanatory Notes of the Harmonized Commodity Description and Coding System are to the 2014 edition.

To that end, plaintiff maintains that "the subject products were conceived, designed, produced, marketed, and sold for 'therapeutic or prophylactic use' to treat persons with medical problems, which is the defining characteristic of a medicament." Pl.'s Br. 20. Plaintiff adds that "[m]edical professionals refer to the deployment of these products as 'nutritional **therapy**,' thus confirming their therapeutic use and value" and that "as FDA-regulated 'medical foods' the subject products are the 'medicine' that doctors will prescribe or recommend to treat children suffering from the referenced diseases." *Id*.

Nutricia argues that in order for defendant to prevail "it must demonstrate that the subject products are not medicaments" and that "[i]t cannot do so, because the tariff provisions, coupled with the record evidence, establish that the subject products are indeed medicaments." *Id*. The court does not agree with this analysis. Even if some definitions of the term "medicaments" were considered broad enough to encompass what plaintiff describes as "nutritional therapy" or "medical food" products, it would not follow that chapter 30, HTSUS necessarily includes these products. GRI 1 requires the court first to determine classification according to "any relative section and chapter notes," as well as the terms of the headings when interpreted according to intended meaning. GRI 1, HTSUS. To rule in favor of plaintiff's claim for classification under heading 3004, the court would need to agree with plaintiff's argument that its preferred classification under heading 3004 is not precluded by a pertinent chapter note, note 1(a) to chapter 30, HTSUS. But the court must reject that argument.

Note 1(a) to chapter 30, HTSUS expressly excludes from chapter 30, and therefore from heading 3004, "[f]oods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters), other than nutritional preparations for intravenous administration (section IV)." The reference to "section IV" indicates that the products described in the note, i.e., "foods . . . other than nutritional preparations for intravenous administration," are to be classified in section IV of the HTSUS, which includes chapter 21, rather than in section VI (which includes chapter 30).

In making an exception to the general exclusion that it applies to chapter 30, note 1(a) specifically references "*nutritional* preparations for intravenous administration." This term necessarily is interpreted to include nutritional preparations administered intravenously to treat or manage a medical condition, typically in a hospital or similar clinical setting. *See* EN 30.03 (specifying that the heading includes "[n]utritional preparations for intravenous administration only, i.e., by injection or drip into a vein."). The implication of this narrow exception to the general exclusion created by note 1(a) to chapter 30, HTSUS is that other "nutritional preparations," e.g., those formulated to be taken orally by persons with specific medical conditions, possibly are within that general exclusion.

Because Nutricia's imported products are not for intravenous administration, the question is whether these products are "foods or beverages" within the meaning of

those terms as used in note 1(a) to chapter 30, HTSUS. The note identifies "dietetic" and "diabetic" foods or beverages as an example of goods that are within the exclusion from chapter 30 created by note 1(a), connoting that even foods specialized for intended use by persons whose medical condition requires a specialized diet fall within the scope of that exclusion. In describing the products encompassed by that exclusion, the chapter note does not distinguish what plaintiff would call "medical foods" from other foods, except for the narrow class of goods comprised of nutritional preparations for intravenous administration.

The uncontested facts demonstrate that the note 1(a) exclusion to chapter 30 applies to the products at issue in this litigation. Plaintiff itself describes the five products as "Medical Foods, which are a unique class of products defined and regulated by the Food and Drug Administration under the Orphan Drug Act, 21 U.S.C. § 360ee." Pl.'s Br. 1. As plaintiff points out, § 360ee defines the term "Medical Food" 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." *Id*. (quoting 21 U.S.C. § 360ee) (emphasis added).

The HS Explanatory Notes, which although not part of U.S. law are indicative of the intended meaning of heading terms and section and chapter notes, further indicate

that note 1(a) to chapter 30 precludes classification of Nutricia's products under heading 3004. The Explanatory Notes for headings 30.03 and 30.04, which are essentially identical, provide as follows:

> The provisions of the heading text do not apply to foodstuffs or beverages such as dietetic, diabetic or fortified foods, tonic beverages or mineral waters (natural or artificial), which fall to be classified **under their own appropriate headings**. This is essentially the case as regards food preparations containing only nutritional substances. The major nutritional substances in food are proteins, carbohydrates and fats. Vitamins and mineral salts also play a part in nutrition.
>
> Similarly foodstuffs and beverages containing medicinal substances are **excluded** from the heading if those substances are added solely to ensure a better dietetic balance, to increase the energy-giving or nutritional value of the product or to improve its flavour, always provided that the product retains its character of a foodstuff or a beverage.
>
> Moreover, products consisting of a mixture of plants or parts of plants or consisting of plants or parts of plants mixed with other substances, used for making herbal infusions or herbal "teas" (e.g., those having laxative, purgative, diuretic or carminative properties), and claimed to offer relief from ailments or contribute to general health and well-being, are also **excluded** from this heading (**heading 21.06**).
>
> Further, this heading **excludes** food supplements containing vitamins or mineral salts which are put up for the purpose of maintaining health or well-being but have no indication as to use for the prevention or treatment of any disease or ailment. These products which are usually in liquid form but may also be put up in powder or tablet form, are generally classified in **heading 21.06** or **Chapter 22**.
>
> On the other hand, the heading covers preparations in which the foodstuff or the beverage merely serves as a support, vehicle or sweetening agent for the medicinal substances (e.g., in order to facilitate ingestion).

EN 30.03, EN 30.04. These Explanatory Notes indicate that note 1(a) to chapter 30 was intended to draw a bright line between the medicaments of chapter 30 and the foods, including specialized foods taken orally by persons with medical needs (including, for example, diabetics), that are to be classified elsewhere in the HS nomenclature. Under the guidance provided by these ENs, a preparation in which "nutritional substances" are present only to support a "medicinal substance" (as described in the last paragraph quoted above) would be classified under HS heading 30.03 or 30.04. Such a product is to be distinguished from a product comprised entirely of nutritional substances (described in the first paragraph quoted above), or in which medicinal substances are present "solely to ensure a better dietetic balance" or "to increase the energy-giving or nutritional value of the product," EN 30.03, EN 30.04 (described in the second paragraph quoted above), which would not. According to this guidance, it is not sufficient for classification within heading 3003 or 3004, HTSUS that a preparation be formulated to treat or manage a medical condition: it must do so by administering a "medicinal substance." If, instead, the management of the condition is effected solely by a combination of "nutritional substances," the preparation is excluded from heading 3003 and 3004 (and from chapter 30 in the entirety) by note 1(a) to chapter 30, HTSUS. As shown by the uncontested facts, Nutricia's products fit that description.

Plaintiff acknowledges that the five products provide "*nutritional* therapy." Pl.'s Br. 28 (emphasis added). All of the ingredients in each of Nutricia's products

(described below) are "nutritional substances." Four of the products in question, "MSUD Lophlex® LQ," "Periflex® Infant," "Periflex® Junior," and "Neocate® Junior," treat one or more medical conditions by means of specially-formulated combinations of multiple amino acids and other ingredients, as described below. Proteins are included within the scope of the term "nutritional substances." *See, e.g.*, EN 30.04. Citing an expert witness report, plaintiff recognizes that "[p]roteins are essential to the growth and function of all living organisms, and are comprised of varying sequences of twenty different amino acids." Pl.'s Br. 5 (citing *Plaintiff's Expert Report of Dr. Jonah Essers* at 9 (May 27, 2022), Pl.'s Br. Ex. 1 ("*Essers Report*")). Plaintiff adds that "[h]umans source proteins (amino acids) by ingesting plant or animal-based foods." *Id*. The fifth product, Ketocal® Liquid, also contains amino acids and manages intractable or refractory epilepsy and Glucose Transporter Type 1 deficiency by providing "a 'ketogenic' diet that is high in fat, low in carbohydrates, and contains controlled proportions of protein." Pl.'s Br. 13 (citing Pl.'s Br. Ex. 5E, at 2).

Nutricia does not contend, and the report of its own expert witness would rebut an assertion that, amino acids are outside of the common and ordinary meaning of the term "nutritional substances." *See* Pl.'s Br. 5 (explaining that humans source amino acids "by ingesting plant or animal-based foods" and, citing *Essers Report* at 9, that "[p]roteins are essential to the growth and function of all living organisms"). The other

ingredients in each of the five products, described below, also are nutritional substances.

Plaintiff states that MSUD Lophlex® LQ contains a combination of 15 amino acids that does not include the "branch chain" amino acids ("BCAA"), which are leucine, valine, and isoleucine. Pl.'s Br. 7. Nutricia explains that BCAA, if present in the diet in more than minimal amounts, are toxic to children who have branched-chain alpha ketoacid dehydrogenase complex (BCKDC) deficiency (also called Maple Syrup Urine Disease or MSUD), an inborn error of the metabolism. *Id*. at 6–7 (citations omitted). The product is formulated to "provide the minimal amount of BCAA needed for life, without providing any excess that elicits toxicity." *Id*. at 8 (citing *Essers Report* at 10). Plaintiff adds that "[o]ther ingredients provided in the formula include: water, apple, grape, blackcurrent [*sic*] and elderberry juice concentrates, which are included to provide carbohydrates needed for energy and taste." *Id*. (citing *Essers Report* at 18 and Pl.'s Br. Ex. 7). Packaging for MSUD Lophlex® LQ, in 4.2-fluid-ounce "pouches," is labeled as "Mixed Berry Blast" and provides as follows:

> A leucine, isoleucine and valine-free, berry flavored ready-to-drink medical food containing mixed fruit juices from concentrate, amino acids, vitamins, trace elements, and some minerals. Contains docosahexaenoic acid (DHA). For the dietary management of proven Maple Syrup Urine Disease (MSUD) in individuals 4 years and older, including pregnant women (in conjunction with standard folic acid supplementation).

Pl.'s Br. Ex. 20A. The label also states: "Contains 44% fruit juice from concentrate and natural flavors."[5] *Id*.

Plaintiff states that Periflex® Infant and Periflex® Junior are used to treat infants and children, respectively, who have Phenylketonuria (PKU), "an inborn error of metabolism," the "prevailing treatment" for which "is a diet low or absent in foods that contain phenylalanine, which is a common amino acid, and the inclusion of certain supplements to provide the minimum amount of phenylalanine required for synthesis

---

[5] The ingredients of MSUD Lophlex® LQ are listed on the label as follows:

> **Ingredients**: Water, apple juice from concentrate (34.1%), grape juice from concentrate (6.9%), blackcurrant juice from concentrate (2.5%), L-lysine acetate, L-proline, citric acid, L-tyrosine, L-arginine, glycine, L-serine, L-aspartic acid, L-alanine, L-threonine, corn syrup solids, L-cystine, L-phenylalanine, dicalcium phosphate, L-histidine, elderberry juice from concentrate (0.6%), maltodextrin, magnesium acetate, N-acetyl L-methionine, L-tryptophan, choline bitartrate, C. cohnii oil*, sugar, microcrystalline cellulose, natural flavor, fruit concentrate (apple, blackcurrant, radish), L-ascorbic acid, taurine, guar gum, lecithin, xanthan gum, M-inositol, potassium sorbate (preservative), artificial sweetener: sucralose, ferrous lactate, artificial sweetener: acesulfame potassium, sodium benzoate (preservative), zinc sulfate, L-carnitine, niacinamide, DL-alpha tocopheryl acetate, calcium D-pantothenate, manganese sulfate, cupric sulfate, thiamine chloride hydrochloride, pyridoxine hydrochloride, vitamin A palmitate, riboflavin, folic acid, potassium iodide, ascorbyl palmitate, mixed tocopherols, sodium molybdate, D-biotin, sodium selenite, chromium chloride, phylloquinone, vitamin D_3, cyanocobalamin.
>
> *A source of docosahexaenoic acid (DHA)

Mem. of Law & Authorities in Supp. of Pl.'s Mot. for Summary J. Ex. 20A (Aug. 31, 2022), ECF Nos. 73 (Conf.), 74 (Public) ("Pl.'s Br.").

of body proteins." *Id*. at 8–9 (quoting Pl.'s Br. Ex. 9 and citing *Essers Report* at 11–12, 19–20, 24).

Periflex® Infant contains a combination of 17 amino acids that does not include phenylalanine and is not naturally found in foods. *Id*. at 9 (citing *Essers Report* at 19 and Pl.'s Br. Ex. 11). "Other ingredients in Periflex® Infant, include: essential vitamins, minerals, fats and carbohydrates."[6] *Id*. at 10 (citing *Essers Report* at 20 and Pl.'s Br. Ex. 11). Sample packaging in a 14-ounce canister is labeled as a powdered infant formula, as follows:

---

[6] The ingredients of Periflex® Infant are listed on the label as follows:

> **Ingredients**: Corn syrup solids, refined vegetable oil (high oleic sunflower, soy, coconut), calcium phosphate dibasic, L-arginine L-aspartate, tri-potassium citrate, L-leucine, L-lysine acetate, L-tyrosine, L-glutamine, L-proline, L-valine, glycine, L-isoleucine, CAEM (an emu[l]sifier), L-threonine, L-serine, L-histidine, L-alanine, sodium chloride, l-cystine, L-tryptophan, L-methionine, magnesium acetate, magnesium L-aspartate, potassium chloride, M. alpina oil*, choline bitartrate, M-inositol, C. cohnii oil**, L-ascorbic acid, ferrous sulfate, zinc sulfate, taurine, L-carnitine, niacinamide, sunflower oil, DL-alpha tocopherol acetate, calcium-d-pantothenate, cupric sulfate, manganese sulfate, pyridoxine hydrochloride, riboflavin, vitamin A acetate, thiamine chloride hydrochloride, ascorbyl palmitate, potassium iodide, chromium sulfate, mixed tocopherols, DL-alpha tocopherol, phylloquinone, sodium molybdate, folic acid, sodium hydrogen selenite, D-biotin, vitamin D_3, cyanocobalamin.
>
> * A source of arachidonic acid(ARA)
>
> ** A source of docosahexaenoic acid (DHA)

Pl.'s Br. Ex. 20B.

> Periflex Infant is a phenylalanine-free, iron-fortified infant formula containing a balance[d] mixture of other essential and non-essential amino acids, carbohydrate, fat, vitamins, minerals and trace elements. Periflex Infant also contains DHA and ARA, which are found in breast milk and are important for infant brain and eye development.

Id. at Ex. 20B. "Directions for Preparation and Use" instruct the consumer to "add five level scoops" to 5 fluid ounces of "warm or cool sterile water." *Id*.

Periflex® Junior contains a combination of 18 amino acids and also "essential vitamins, minerals, fats and carbohydrates."[7] *Id*. at 10 (citing *Essers Report* at 20–21 and Pl.'s Br. Ex. 14). Sample packaging in a 16-ounce canister is labeled as follows:

> **Periflex Junior** is a phenylalanine-free powder containing a balanced mixture of the other essential and non-essential amino acids, carbohydrate, fat, vitamins, minerals and trace elements. For the dietary management of phenylketonuria in toddlers and young children.

---

[7] The ingredients of Periflex® Junior are listed on the label as follows:

> **Ingredients**: Corn syrup solids, canola oil, high oleic safflower oil, L-glutamine, L-proline, L-asparagine, L-lysine hydrochloride, tripotassium citrate, L-tyrsoine, L-leucine, disodium hydrogen phosphate, L-valine, L-serine, L-isoleucine, tricalcium citrate, tricalcium phosphate, L-alanine, maltodextrin, L-threonine, sugar, magnesium hydrogen phosphate, L-citrulline, L-arginine, L-cystine, choline bitartrate, taurine, fractionated coconut oil, CAEM (an emulsifier), L-histidine, L-methoionine, L-tryptophan, L-ascorbic acid, M-inositol, ferrous sulfate, zinc sulfate, L-carnitine, DL-alpha tocopheryl acetate, manganese sulfate, niacinamide, calcium D-pantothenate, cupric sulfate, thiamine chloride hydrochloride, pyridoxine hydrochloride, riboflavin, vitamin A acetate, folic acid, potassium iodide, chromium chloride, sodium selenite, sodium molybdate, phylloquinone, D-biotin, vitamin D_3, cyanocobalamin.

Pl.'s Br. Ex. 20C.

Id. at Ex. 20C. The "Directions for Preparation and Use" inform the consumer that "[i]ntake is to be determined by a healthcare professional" and instruct the consumer to "add the prescribed amount of powder" according to specified dilution guidelines. *Id*.

Plaintiff's motion describes Neocate® Junior as a product "used to treat patients who suffer from: (1) Eosinophilic Esophagitis (EoE), (2) Short Bowel Syndrome (SBS), . . . as well as other diseases and disorders." *Id*. at 10 (citing *Essers Report* at 25–29). It contains a combination of 19 amino acids, "targeting the unique biology of a specific disease state." *Id*. at 12 (citing *Essers Report* at 20–21 and Pl.'s Br. Ex. 16). "Other ingredients in the formula include: essential vitamins, minerals, fats and carbohydrates."[8] *Id*. (citing *Essers Report* at 21 and Pl.'s Br. Ex. 16).

---

[8] The ingredients of Neocate® Junior are listed on the label as follows:

> **Ingredients**: Corn syrup solids (52%), refined vegetable oil (palm kernel and/or coconut oil (8%), canola oil (8%), high oleic safflower oil (8%)), L-arginine (2.4%), L-glutamine (2.3%), L-lysine L-aspartate (2%), and less than 2% of each of the following: tripotassium citrate, calcium phosphate dibasic, L-leucine, L-phenylalanine, L-proline, silicon dioxide, L-valine, glycine, L-isoleucine, N-acetyl-L-methionine, L-threonine, mono and diglycerides, sodium chloride, L-histidine, L-serine, L-alanine, magnesium acetate, calcium phosphate tribasic, choline bitartrate, L-tryptophan, L-tyrosine, diacetyl tartaric acid esters of mono & diglycerides, M-inositol, L-ascorbic acid, L-cystine, propylene glycol alginate, taurine, ferrous sulfate, L-carnitine, zinc sulfate, DL-alpha tocopheryl acetate, niacinamide, calcium D-pantothenate, magnesium sulfate, cupric sulfate, riboflavin, thiamine chloride hydrochloride, pyridoxine hydrochloride, vitamin A acetate, folic acid, potassium iodide,

(continued…)

A Neocate® Junior package, a 14.1-ounce canister, is labeled as follows:

> **Neocate Junior** provides complete or supplemental nutritional support for children with gastrointestinal impairment due to cow milk allergy or other medical conditions of the gastrointestinal tract.

Id. at Ex. 20D. The label also states:

> Amino Acid-Based Nutritionally Complete Powdered Formula
> Hypoallergenic
> For the dietary management of cow and soy milk allergy, multiple food protein intolerance, eosinophilic esophagitis, short bowel syndrome, and conditions of gastrointestinal tract impairment and malabsorption requiring an elemental diet
> A Medical Food
> Unflavored
> Powder – Add Water

Id. The "Directions for Preparation and Use" inform the consumer: "Suggested intake to be determined by a healthcare professional" and instruct the consumer to "add the prescribed amount of **Neocate Junior**" according to specified dilution guidelines. *Id*.

The fifth product, Ketocal® Liquid, "is unique in that it provides a 4:1 ratio of fat calories to 'non-fat' protein and carbohydrate calories." *Id*. at 13 (citing *Essers Report* at 21). It "is used to treat patients who suffer from: (1) Intractable/Refractory Epilepsy, [or] (2) Glucose Transporter Type 1 Deficiency (GLUT 1)" who require a "'ketogenic' diet that is high in fat, low in carbohydrates, and contains controlled proportions of

---

> chromium chloride, sodium molybdate, sodium selenite, phylloquinone, biotin, vitamin D_3, cyanocobalamin.

Pl.'s Br. Ex. 20D.

protein." *Id*. at 12–13 (citing Pl.'s Br. Ex. 5E, at 1–3). Plaintiff states that "[t]he fats in Ketocal® are: Refined vegetable oil (high oleic sunflower, soy, palm), alpina oil, C. Cohnii oil, mono and diglycerides, and soy lecithin" and that "[c]arnitine and taurine are added to further optimize digestion and metabolism." *Id*. at 13 (citing *Essers Report* at 21). "Other ingredients are: water, proteins, minimal carbohydrates, vitamins, minerals and fiber."[9] *Id*. at 14 (citing Pl.'s Br. Ex. 18).

---

[9] The ingredients of vanilla-flavored Ketocal® Liquid are listed on the label of outer packaging (containing 27 8-ounce individual containers) as follows:

> **Ingredients**: water, refined vegetable oil (high oleic sunflower, soy, palm), sodium caseinate (milk), whey protein concentrate (milk), soy fiber, corn starch, inulin, CAEM (an emulsifier), artificial flavor, dipotassium phosphate, gum arabic, calcium chloride, m. alpina oil*, magnesium acetate, potassium chloride, c. cohnii oil**, microcrystalline cellulose, sugar, fructooligosaccharide, L-ascorbic acid, calcium phosphate monobasic, mono and diglycerides, trisodium citrate, sodium hydroxide, choline chloride, L-cystine, calcium phosphate dibasic, artificial sweetener: sucralose, propylene glycol alginate, ferrous lactate, L-carnitine, taurine, M-inositol, L-tryptophan, zinc sulfate, DL-alpha tocopheryl, soy lecithin, niacinamide, calcium D-pantothenate, manganese sulfate, ascorbyl palmitate, cupric sulfate, thiamine chloride hydrochloride, pyridoxine hydrochloride, riboflavin, vitamin A acetate, mixed tocopherols, DL-alpha tocopherol, folic acid, potassium iodide, chromium chloride, sodium selenite, sodium molybdate, phylloquinone, D-biotin, vitamin D_3, cyanocobalamin.
>
> *A source of Arachidonic Acid (ARA)
> ** A source of docosahexaenoic acid (DHA)

Pl.'s Br. Ex. 20E. A package of unflavored Ketocal® Liquid is also illustrated. *Id*.

An 8-ounce package of the product is labeled as Ketocal® 4:1 LQ Multi Fiber and states: "A ready-to-feed 4:1 ratio ketogenic formula, for the dietary management of intractable epilepsy." *Id*. at Ex. 20E.

The descriptions and labeling of Nutricia's products demonstrate that each of these five products is comprised entirely of "nutritional substances." *See* EN 30.03, EN 30.04 (distinguishing between "nutritional substances" and "medicinal substances"). Note 1(a) to chapter 30, HTSUS, by plain meaning and as interpreted according to EN 30.03 and EN 30.04, excludes from chapter 30 all such products. GRI 1 requires the court to give effect to note 1(a) to chapter 30 and thereby exclude Nutricia's products from the scope of heading 3004, HTSUS.

Nutricia argues that note 1(a) to chapter 30, HTSUS does not defeat its claim for classification under heading 3004, essentially on the premise that this case presents a special situation under which chapter note 1(a) to chapter 30 must be disregarded. According to plaintiff's argument, the court should compare the heading the government advocates, heading 2106, HTSUS, with its preferred heading, heading 3004, HTSUS, and choose the latter based on the "relative specificity" of the two headings according to GRI 3(a), HTSUS ("The heading which provides the most specific description shall be preferred to headings providing a more general description."). By elevating GRI 3(a) over GRI 1, which takes precedence, this argument misinterprets the GRIs.

Plaintiff bases its argument on note 1(f) to chapter 21, HTSUS, which excludes from chapter 21 (and therefore from heading 2106) "products of heading 3003 or 3004." According to Nutricia's argument, "[t]he chapter 21 and 30 notes are mutually exclusive" and "[t]he [Court of Appeals for the] Federal Circuit has held that when there are two mutually exclusive chapter notes, the product must be classified according to the terms of the headings, GRI 1 and GRI 3(a), and the most specific provision prevails." Pl.'s Br. 37 (citing *Bauer Nike Hockey USA, Inc. v. United States*, 393 F.3d 1246, 1252–53 (Fed. Cir. 2004) (citing *Sharp Microelectronics Tech., Inc. v. United States*, 122 F.3d 1446, 1450–51 (Fed. Cir. 1997))). *See also* Pl.'s Resp. to Def.'s Cross-Mot. for Summary J. and Reply to Def.'s Resp. to Pl.'s Mot. for Summary J. 17 (Dec. 2, 2022), ECF Nos. 86 (Conf.), 83 (Public) ("Pl.'s Resp.") ("Note 1(a) cannot be used to exclude products from chapter 30 in this case because Note 1(f) to chapter 21 excludes goods classified under heading 3004 from chapter 21.").

According to plaintiff, "when there are mutually exclusive chapter notes classification is first determined according to the relative specificity of the competing headings' text." *Id*. (quoting *Bauer Nike Hockey USA, Inc.*, 393 F.3d at 1252 n.6) ("Resorting to the exclusionary note before applying the rule of specificity . . . would yield the somewhat arbitrary result that the subject merchandise could be classified under different chapters based solely on which chapter the analysis began.").

Plaintiff's "relative specificity" argument is misguided in failing to give effect to GRI 1, which directs the inquiry to the terms of the headings and the relative section and chapter notes, with the section or chapter notes and the heading terms given equal consideration. A critical flaw in plaintiff's argument is that note 1(a) to chapter 30, which limits the scope of heading 3004 so as to exclude plaintiff's goods, and note 1(f) to chapter 21, which limits the scope of heading 2106, are not "mutually exclusive."

Note 1(a) to chapter 30, HTSUS excludes from that chapter a defined class or kind of goods: "[f]oods or beverages . . . other than nutritional preparations for intravenous administration." In contrast, note 1(f) to chapter 21, HTSUS, which states that chapter 21 "does not cover: . . . Yeast put up as a medicament or other products of heading 3003 or 3004," excludes by name one class or kind of goods (yeast put up as a medicament) but, as is pertinent here, also excludes the "products *of* heading 3003 or *3004*" (emphasis added). In doing so, note 1(f) to chapter 21, HTSUS requires a classification determination to be made *before* it can be decided *whether* the exclusion in note 1(f) to chapter 21 applies. Therefore, the court must consider the scope of heading 3004 as interpreted according to note 1(a) to chapter 30 as well as considering the effect, if any, of note 1(f) to chapter 21. When it does so, it must conclude that there is no occasion to apply note 1(f) to chapter 21 where, as here, a good is excluded from heading 3004 by operation of note 1(a) to chapter 30. In other words, because note 1(a) to chapter 30 precludes the court from considering heading 3004 as a candidate heading

for Nutricia's products, GRI 1 eliminates heading 3004 from consideration, and the issue of relative specificity of the competing headings, which is the subject of GRI 3(a), does not arise. The choice between heading 3004 and heading 2106 is determined conclusively by GRI 1, not GRI 3(a).

The problem addressed in *Bauer Nike Hockey USA, Inc.*, under which the "arbitrary result that the subject merchandise could be classified under different chapters based solely on which chapter the analysis began," 393 F.3d at 1252 n.6, is not presented by this case. The court has begun its analysis by first considering heading 3004, which is plaintiff's preferred alternative to the government's classification. But the same result would obtain were the court to consider heading 2106 in the first instance. Note 1(f) to chapter 21, HTSUS would require the court, in doing so, to decide whether Nutricia's products actually *are* products of heading 3004. The court must apply GRI 1 in making this determination, which entails giving effect to note 1(a) to chapter 30, under which heading 3004 is eliminated from consideration and there is no occasion to apply note 1(f) to chapter 21. The court, therefore, must reject the premise of plaintiff's argument, under which note 1(a) to chapter 30, HTSUS essentially is disregarded.

In support of its argument in favor of classification under heading 3004, plaintiff also argues that heading 3004 is a "use" provision (or "principal use" provision) and that the court, in determining the classification of the goods at issue, therefore must

apply additional U.S. rule of interpretation 1(a), HTSUS ("a tariff classification controlled by use (other than actual use) is to be determined in accordance with the use in the United States at, or immediately prior to, the date of importation, of goods of that class or kind to which the imported goods belong, and the controlling use is the principal use."). Pl.'s Br. 29 (citations omitted). Plaintiff argues that "[e]ach of the products is used as nutrition therapy to treat young children with specific and dangerous medical conditions or disorders" and "have no other use." *Id*. at 30 (citation omitted). According to Nutricia's argument, the products at issue are of the same class or kind as medicaments and, accordingly, must be classified by operation of additional U.S. rule of interpretation 1(a) as medicaments under heading 3004, HTSUS. *Id*. (citations omitted).

Heading 3004 (like heading 3003) arguably contains language implicating use but is based on an *eo nomine* tariff term, "Medicaments . . . ." In any event, plaintiff's argument overlooks that in this instance there is no occasion to apply additional U.S. note of interpretation 1(a) (which applies only "[i]n the absence of special language or context which otherwise requires") because heading 3004 is precluded from consideration by GRI 1. GRI 1 requires the court to apply note 1(a) to chapter 30 to exclude Nutricia's imported products from chapter 30, HTSUS and, therefore, from heading 3004, HTSUS regardless of whether heading 3004 possibly could be considered to be a use provision.

2. Heading 2106 Is the Correct Heading for Nutricia's Products

Based on the uncontested facts as taken from the submissions of the parties in support of their cross-motions for summary judgment, there can be no genuine dispute over whether the five "medical foods" at issue in this case, being specially-formulated combinations of nutritional substances, are "food preparations." The next question, then, is whether any tariff provision excludes the products at issue from chapter 21, HTSUS, or specifically, from heading 2106, HTSUS. The court concludes there is not.

Note 1 to chapter 21 ("Miscellaneous edible preparations") excludes from the chapter certain foods and food preparations but does not exclude "medical foods" such as those at issue in this case. In addition, the Explanatory Note to HS heading 21.06 lists various classes or kinds of products covered by the heading and distinguishes from them some that are not covered. The EN provides as follows:

> Provided that they are not covered by any other heading of the Nomenclature, this heading covers:
>
> * * *
>
> (16) Preparations, often referred to as food supplements, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing added vitamins and sometimes minute quantities of iron compounds. These preparations are often put up in packagings with indications that they maintain general health or well-being. *Similar preparations, however, intended for the prevention or treatment of diseases or ailments are* ***excluded (heading 30.03 or 30.04)***.

EN 21.06 ¶ 16 (emphasis added). The issue presented by this EN is whether the reference in the third sentence to "[s]imilar preparations" could be read broadly to describe the products at issue in this case. Plaintiff argues that the court should

interpret the third sentence to apply to its medical food products, resulting in classification under heading 3004 rather than heading 2106, HTSUS. Pl.'s Br. 39. The court disagrees.

The paragraph quoted above from EN 21.06 addresses "food supplements" and "[s]imilar preparations." It must be read in context with HS note 1(a) to chapter 30 (and, accordingly, with note 1(a) to chapter 30, HTSUS), which expressly excludes all "food supplements" from chapter 30. Thus, food supplements fall within chapter 21, while certain products that are "similar" to food supplements (but are to be distinguished from food supplements) and are intended to treat a specific disease or ailment are "medicaments" or "medicinal substances" within the intended scope of HS heading 30.03 or 30.04. A food or beverage intended to treat a specific disease or ailment is not within that scope, unless it is based on a "medicinal substance" that, as instructed by EN 30.03 and EN 30.04, is not "added solely to ensure a better dietetic balance, to increase the energy-giving or nutritional value of the product or to improve its flavour." EN 30.03, EN 30.04.

As shown by the ingredient statements (presented above), each of the products at issue in this litigation is formulated from a large number of different nutritional substances but is not based on a "medicinal substance" as required for classification within heading 3003 or 3004, HTSUS. The implied premise of the argument Nutricia makes in reliance on EN 21.06 is that its imported products should not be considered to

be "foods" or "food supplements" within the meaning of note 1(a) to chapter 30, HTSUS. But the facts plaintiff itself puts forth in support of its summary judgment motion, discussed at length above, demonstrate that these are food products, comprised of nutritional substances, that note 1(a) to chapter 30, HTSUS excludes from that chapter.

In summary, the five products at issue are "food preparations" and are not "medicaments" of heading 3004, HTSUS. Because no other heading within chapters 1 to 97 of the HTSUS specifies or includes these food preparations, heading 2106 ("Other food preparations, not elsewhere specified or included") is the correct heading by operation of GRI 1.

G. Application of GRI 6, HTSUS to Determine the Correct Subheading

The products at issue are not "[p]rotein concentrates or textured protein substances" of subheading 2106.10, HTSUS and thus are classified in six-digit subheading 2106.90, HTSUS ("Other:"). The uncontested facts do not demonstrate that they are described by any of the eight-digit subheadings between 2106.90.03 and 2106.90.95, HTSUS, inclusive. Therefore, the correct eight-digit subheading is subheading 2106.90.99, HTSUS ("Food preparations not elsewhere specified or included: Other: Other: Other: Other: Other: Other), subject to duty at 6.4% *ad valorem*. This is the tariff classification Customs determined upon the liquidation of the entries

and the tariff classification defendant advocates in support of its cross-motion for summary judgment.

H. Subheading 9817.00.96, HTSUS Does Not Apply to Nutricia's Products

Plaintiff claims, in the alternative, that even if its products are not "medicaments" of heading 3004, HTSUS, they still would qualify for duty-free treatment under a special tariff provision, subheading 9817.00.96, HTSUS, which applies to "[a]rticles specially designed or adapted for the use or benefit of the blind or other physically or mentally handicapped persons; parts and accessories (except parts and accessories of braces and artificial limb prosthetics) that are specially designed or adapted for use in the foregoing articles: . . . Other."

In support of its argument that the persons for whom its medical foods are produced are "physically or mentally handicapped persons," Nutricia directs the court's attention to U.S. note 4(a) to subchapter XVII, chapter 98, HTSUS, which defines the term "physically or mentally handicapped persons" as follows:

> For purposes of subheadings 9817.00.92, 9817.00.94 and 9817.00.96, the term "blind or other physically or mentally handicapped persons" includes any person suffering from a permanent or chronic physical or mental impairment which substantially limits one or more major life activities, such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, or working.

The court finds no merit in plaintiff's alternate classification claim. U.S. note 4(b) to subchapter XVII, chapter 98, HTSUS provides that subheading 9817.00.96 does not cover "(i) articles for acute or transient disability; (ii) spectacles, dentures, and cosmetic

articles for individuals not substantially disabled; (iii) therapeutic and diagnostic articles; or (iv) medicine or drugs." Plaintiff bases its argument on the premise that the persons for whom its medical foods are produced are "physically or mentally handicapped persons" and that these food products, even if not considered "medicine or drugs," nevertheless are not "therapeutic . . . articles" within the meaning of U.S. note 4(b)(iii) to subchapter XVII, chapter 98, HTSUS.

Defendant argues that the medical foods are "therapeutic" within the meaning of the note. Def.'s Br. 31. The undisputed facts provide some support for that argument. Plaintiff informs the court—and it is not contested—that the five products are "indicated for use in the treatment of a variety of diseases, predominantly in very young children," that "in some instances they are the only, or primary, available treatment to ameliorate these severe and sometimes fatal conditions" and that "[m]edical professionals refer to the deployment of these products as 'nutritional **therapy**,' thus confirming their therapeutic use and value." Pl.'s Br. 20.

Nevertheless, plaintiff urges the court to give the word "therapeutic" a different, and narrower, meaning when construing U.S. note 4(b)(iii) to subchapter XVII, chapter 98, HTSUS. According to Nutricia's argument, the word "therapeutic" as it appears in U.S. note 4(b) to subchapter XVII, chapter 98, HTSUS is confined to those articles that heal or cure a disability rather than treat or manage it. Pl.'s Resp. 34. Plaintiff argues that "U.S. note 4(a) and subheading 9817.00.96 were implemented as

part of the Educational, Scientific, and Cultural Materials Importation Act of 1982, which implemented the Nairobi Protocol" and that "[t]hese provisions were intended to liberally and broadly encourage the importation of articles for hand[ica]pped persons." *Id*. (citations omitted).

In support of its argument, Nutricia quotes *Richards Medical Co. v. United States*, 910 F.2d 828, 831 (Fed. Cir. 1990) ("Congress intended to encourage the importation of that merchandise which is designed to compensate for, or help adapt to, the handicapped condition. At the same time, Congress did not want to allow duty-free importation of merchandise which is used to heal or cure the condition causing the handicap."). Pl.'s Resp. 35. The facts of the case (decided under the previous Tariff Schedule of the United States but involving an antecedent provision to subheading 9817.00.96, HTSUS) are inapposite. The Court of Appeals for the Federal Circuit ("Court of Appeals") was considering whether the duty-free provision at issue applied to an imported hip prosthesis. The court recognized that the term "'therapeutic' has many different meanings and is subject to both broad and narrow interpretations." *Richards Medical Co.*, 910 F.2d at 830. Reading the term narrowly in light of the intent of the provision, the Court of Appeals affirmed a factual finding of the Court of International Trade in the decision being appealed, under which the prosthetic hip allowed a patient to "better compensate for the handicap" but did not cure the patient of an underlying condition, such as arthritis. Based on that finding, the Court of

Appeals concluded that the imported article was not "therapeutic" so as to preclude classification within the duty-free provision.

The flaw in plaintiff's alternate classification claim does not turn on whether the medical foods are other than "therapeutic," in the narrow sense of that term as urged upon the court by Nutricia. Instead, the error in plaintiff's classification analysis is its overly broad construction of the terms of the duty-free provision, considered on the whole. Read in conjunction with U.S. note 4(a) to subchapter XVII, chapter 98, HTSUS, the duty-free provision in subheading 9817.00.96 is limited to "[a]rticles specially designed or adapted for the use or benefit" of a "handicapped" person, i.e., "a person suffering from a permanent or chronic physical or mental impairment which substantially limits one or more major life activities, such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, or working." Plaintiff interprets the terms "handicapped" and "physical or mental impairment" so broadly as to include virtually *any* serious medical condition, despite the words of limitation used to delineate the scope of the provision. Moreover, plaintiff interprets the term "[a]rticles specially designed or adapted for . . ." so broadly as to include "foods" or "beverages" designed to treat or manage (but not cure) such medical condition, provided they are not "medicines or drugs." The weakness in plaintiff's argument lies in its tortured interpretation of each of these terms, considered together and in context. Nothing in the terms of subheading 9817.00.96, HTSUS provides or

even connotes that Congress, addressing the needs of "the blind or other mentally or physically handicapped persons" for "articles specially designed or adapted" for their "use or benefit," intended the scope of the subheading to be so broad as to cover foods, food supplements, or nutritional substances or ingredients of any type.[10] The court, therefore, rejects plaintiff's alternate claim for classification of the five products in subheading 9817.00.96, HTSUS.

III. CONCLUSION

The court concludes that there is no genuine dispute as to any material fact and that plaintiff has not demonstrated that "the government's classification is incorrect." *Jarvis Clark*, 733 F.2d at 876. Therefore, defendant is entitled to judgment as a matter of law. Accordingly, the court will deny plaintiff's motion for summary judgment, grant defendant's cross-motion, and enter summary judgment in favor of defendant.

/s/ Timothy C. Stanceu
Timothy C. Stanceu
Judge

Dated: December 4, 2023
New York, New York

[10] Illustrative of the limited scope of the provision is the formulation of the related subheadings 9817.00.92 and 9817.00.96, HTSUS (which share the same general article description with subheading 9817.00.98) and are limited to physical articles ("Books, music, and pamphlets, in raised print" and "Braille tablets, cubarithms, and special apparatus, machines, presses, and types") as opposed to substances (e.g., liquids or powders) or foods. Under plaintiff's interpretation, for example, a food or food supplement specially designed to manage (but not cure) a severe visual impairment would qualify under the provision even though subheadings 9817.00.92 and 9817.00.96, HTSUS would not describe it.