

United States Court of Appeals for the Federal Circuit

SIGMA-TAU HEALTHSCIENCE, INC., AKA SIGMA-TAU HEALTHSCIENCE, LLC,
Plaintiff-Appellant

v.

UNITED STATES,
Defendant-Appellee

2016-1125

Appeal from the United States Court of International Trade in No. 1:11-cv-00093-GWC, Judge Gregory W. Carman.

Decided: September 26, 2016

JOHN C. MONICA, JR., Porter Wright Morris & Arthur, Washington, DC, argued for plaintiff-appellant. Also represented by LESLIE ALAN GLICK, CHRISTOPHER YOOK.

ALEXANDER J. VANDERWEIDE, Commercial Litigation Branch, Civil Division, United States Department of Justice, New York, NY, argued for defendant-appellee. Also represented by AMY M. RUBIN; BENJAMIN C. MIZER, JEANNE E. DAVIDSON, Washington, DC; YELENA SLEPAK, Office of Assistant Chief Counsel, U.S. Customs and

Border Protection, United States Department of Homeland Security, New York, NY.

Before NEWMAN, DYK, and REYNA, *Circuit Judges*.
DYK, *Circuit Judge*.

This Customs case concerns the classification of two chemical products, both stabilized forms of the compound carnitine, which were imported into the United States by Sigma-Tau HealthScience, Inc., a.k.a. Sigma-Tau HealthScience, LLC (“Sigma-Tau”). United States Customs and Border Protection (“Customs” or “the government”) initially classified these products under a subheading of the Harmonized Tariff Schedule of the United States (“HTSUS”) that carries a duty. Sigma-Tau protested, arguing that the products should be classified under HTSUS heading 2936 (which encompasses “provitamins and vitamins”), subheading 2936.29.50, a duty-free classification.

The Court of International Trade (“CIT”) concluded that Sigma-Tau’s products should be classified under a different subheading, 2923.90.00, making them ineligible for duty-free treatment. *Sigma-Tau HealthScience, Inc. v. United States* (“Sigma-Tau”), 98 F. Supp. 3d 1365, 1377–78 (Ct. Int’l Trade 2015). On appeal, the parties agree that the only issue is whether Sigma-Tau’s products are properly classified as vitamins under HTSUS heading 2936. We agree with Sigma-Tau that its carnitine products are properly classified under that heading, because carnitine is a vitamin in neonates. We therefore reverse and remand.

BACKGROUND

Customs classifications according to the headings and subheadings of the HTSUS determine the duties that importers must pay to the United States. The question

here is the appropriate classification of Sigma-Tau's carnitine products.

Carnitine¹ is a naturally occurring amino acid derivative and an important nutrient in the human body, where it serves to transport long-chain fatty acids into mitochondria, the centers for energy production within each cell. Our bodies obtain carnitine exogenously, from food, and also produce it endogenously, by breaking down and reforming protein. (According to the *Webster Comprehensive Dictionary*, an "exogenous" compound originates outside the organism, while an "endogenous" compound is one originating or produced internally. See *Exogenous*, *Webster Comprehensive Dictionary* (Int'l ed. 2001); *Endogenous*, *id.*) Stabilized forms of carnitine are formulated into tablets or capsules and sold as nutritional supplements; they can also be incorporated into drinks, protein bars, and other products for human consumption. Carnitine is sometimes referred to as "vitamin Bt"; for example, the online version of *Merriam Webster's Medical Dictionary* identifies "vitamin Bt" as a synonym of "carnitine." J.A. 1279. While carnitine is an organic compound, it is not listed by name in any heading or subheading of HTSUS Chapter 29, which covers "Organic Chemicals."

Sigma-Tau imports carnitine products into the United States. The two carnitine products at issue are acetyl L-carnitine taurinate hydrochloride with 1.5% silica, which

¹ Carnitine is a chiral compound and exists in two distinct stereoisomeric forms: the biologically active L-carnitine enantiomer and the inactive D-carnitine enantiomer. Sigma-Tau's products specifically contain L-carnitine, and the parties agree that L-carnitine is the biologically and commercially significant enantiomer at issue in this case. For simplicity, we refer hereinafter to L-carnitine simply as "carnitine."

Sigma-Tau sells under the brand name “L-Tauro,” and glycine propionyl L-carnitine hydrochloride USP with 1.5% silica, which Sigma-Tau sells under the brand name “GlycoCarn.” These products, white powders manufactured in Italy, were imported in bulk. In 2010, Customs classified these products under HTSUS subheading 3824.90.92, which covers “Prepared binders for foundry molds or cores; chemical products and preparations of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included: Other: Other: Other: Other.” That subheading carries a 5% duty. Sigma-Tau timely protested this classification, arguing that the products qualify as vitamins under HTSUS subheading 2936.29.50, which covers “Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent: Vitamins and their derivatives, unmixed: Other vitamins and their derivatives: Other: Other.” That subheading is duty-free.

Sigma-Tau brought suit in the CIT, requesting that the court set aside Customs’ classification decision and hold that the L-Tauro and GlycoCarn products are properly classified as vitamins under HTSUS subheading 2936.29.50 (and, therefore, deserving of duty-free treatment). Sigma-Tau also requested that the CIT instruct Customs to re-liquidate the entries for these products and to award damages for alleged overpayment of duties. Sigma-Tau moved for summary judgment. The government cross-moved for summary judgment, arguing that Customs’ initial classification of the merchandise under HTSUS heading 3824 was erroneous but that HTSUS subheading 2923.90.00 (covering “Quaternary ammonium salts and hydroxides; lecithins and other phosphoamino-lipids, whether or not chemically defined: Other”), not 2936.29.50, was in fact the proper classification.

The CIT found that Sigma-Tau's products were *prima facie* classifiable both as vitamins under HTSUS heading 2936 and as quaternary ammonium salts under heading 2923. *Sigma-Tau*, 98 F. Supp. 3d at 1374–76. Where an item is *prima facie* classifiable under more than one heading, the General Rules of Interpretation provide guidance as to which heading should be used. *See Dell Prods. LP v. United States*, 642 F.3d 1055, 1057 (Fed. Cir. 2011). Relying on HTSUS General Rule of Interpretation 3 (“GRI 3”), which specifies that when “goods are, *prima facie*, classifiable under two or more headings” “[t]he heading which provides the most specific description shall be preferred to headings providing a more general description,” HTSUS, General Notes, at 1, the CIT concluded that “the term ‘quaternary ammonium salts’ more specifically describes L-Carnitine than ‘vitamins’” and thus that Sigma-Tau’s products were properly classified as quaternary ammonium salts under subheading 2923.90.00, *Sigma-Tau*, 98 F. Supp. 3d at 1377.

The CIT consequently granted summary judgment in favor of the government and denied Sigma-Tau’s motion for summary judgment. *Id.* at 1378. Sigma-Tau appeals, asking us to hold that the proper classification of its merchandise is under HTSUS subheading 2936.29.50, as a vitamin. We have jurisdiction under 28 U.S.C. § 1295(a)(5).

DISCUSSION

“The interpretation of the headings and subheadings of the HTSUS is a question of law, which we review without deference.” *Deckers Corp. v. United States*, 532 F.3d 1312, 1314 (Fed. Cir. 2008); *see also Airflow Tech., Inc. v. United States*, 524 F.3d 1287, 1290 (Fed. Cir. 2008). “A classification decision involves two underlying steps: (1) determining the proper meaning of the tariff provisions, which is a question of law; and (2) determining which heading the particular merchandise falls within,

which is a question of fact.” *Deckers*, 532 F.3d at 1314–15. “We review questions of law de novo, including the interpretation of the terms of the HTSUS, whereas factual findings of the Court of International Trade are reviewed for clear error.” *Id.* at 1315; *see also La Crosse Tech., Ltd. v. United States*, 723 F.3d 1353, 1358 (Fed. Cir. 2013). However, “if there is no genuine dispute over the nature of the merchandise, . . . the proper classification under which it falls [is] the ultimate question in every classification case and one that has always been treated as a question of law.” *Bausch & Lomb, Inc. v. United States*, 148 F.3d 1363, 1366 (Fed. Cir. 1998); *see also Gen. Elec. Co.-Med. Sys. Grp. v. United States*, 247 F.3d 1231, 1235 (Fed. Cir. 2001).

The government concedes that the CIT erred when it applied the rule of relative specificity of GRI 3 to classify Sigma-Tau’s products. The government acknowledges that Note 3 to Chapter 29 of the HTSUS (“Chapter Note 3”) is instead applicable. Chapter Note 3 specifies that “[g]oods which could be included in two or more of the headings of this chapter are to be classified in that one of those headings which occurs last in numerical order.” HTSUS, Ch. 29, Note 3, at 29–1. We have held that “[t]he Section and Chapter Notes [of the HTSUS] are not optional interpretive rules, but are statutory law.” *BenQ Am. Corp. v. United States*, 646 F.3d 1371, 1376 (Fed. Cir. 2011) (internal quotation marks omitted). Consequently, if Sigma-Tau’s merchandise is *prima facie* classifiable as both a quaternary ammonium salt (HTSUS heading 2923) and as a vitamin (HTSUS heading 2936), Chapter Note 3 dictates that it be classified as the latter, as 2936 “occurs last in numerical order.”

Thus, the only issue before us is whether Sigma-Tau’s L-Tauro and GlycoCarn products are *prima facie* classifiable as vitamins under HTSUS heading 2936. If they are, that heading applies; if they are not, heading 2923 ap-

plies, as both sides agree that the products are *prima facie* classifiable as quaternary ammonium salts.²

I

We first address the government's contention that the products are not vitamins because they contain stabilizers. The two products at issue are stabilized forms of carnitine: acetyl L-carnitine taurinate hydrochloride with 1.5% silica (L-Tauro) and glycine propionyl L-carnitine hydrochloride, USP with 1.5% silica (GlycoCarn). The CIT treated the products as equivalent to carnitine itself. At the CIT, the parties agreed that this was the correct approach. "The parties agree that the proper classifica-

² Before the CIT, Sigma-Tau argued that even if classified as quaternary ammonium salts under HTSUS heading 2923, its L-Tauro and GlycoCarn products should nonetheless qualify for "K designation" and thereby be granted duty-free treatment because "carnitine" is listed in the Pharmaceutical Appendix to the HTSUS. "General Note 13 [of the HTSUS] permits duty free treatment of certain pharmaceutical products if three requirements are met . . ." *Forest Labs., Inc. v. United States*, 476 F.3d 877, 882 (Fed. Cir. 2007). One requirement of General Note 13 is that "the merchandise is listed in the Pharmaceutical Appendix of the tariff schedule." *Id.*

The CIT concluded that while carnitine itself is indeed listed in the Pharmaceutical Appendix, the taurine and glycine components of L-Tauro and GlycoCarn, respectively, are not listed, making L-Tauro and GlycoCarn ineligible for K designation and thus ineligible for duty-free treatment under General Note 13. *Sigma-Tau*, 98 F. Supp. 3d at 1377. Sigma-Tau does not appeal this aspect of the CIT's judgment. The inclusion of carnitine in the Pharmaceutical Appendix is unrelated to the question of whether carnitine is *prima facie* classifiable as a "vitamin" under HTSUS heading 2936.

tion of the two products at issue hinges upon the primary and only active component of the products, L-Carnitine.” *Sigma-Tau*, 98 F. Supp. 3d at 1370. In its briefing at the CIT, the government described “L-carnitine (or carnitine)” as “the only biologically active component of the two products at issue” and indicated that the other chemical components serve merely as stabilizers, which “render the two carnitine-based products at issue chemically neutral and stable.” J.A. 336.

On appeal, the government agrees that carnitine is “the sole biologically active component of L-Tauro and GlycoCarn” but now argues, apparently for the first time, that “the court erred when it undertook a classification analysis of L-Carnitine only, and not the actual products in their imported condition,” i.e., carnitine combined with stabilizing ingredients. Appellee’s Br. at 28. The government does not articulate a theory as to how the presence of any particular stabilizing component of L-Tauro or GlycoCarn (e.g., taurine, glycine, or silica) renders the products non-vitamins.

The government’s argument comes too late and is therefore waived. “Our precedent generally counsels against entertaining arguments not presented to the district court.” *Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1322 (Fed. Cir. 2008); *see also Singleton v. Wulff*, 428 U.S. 106, 120 (1976). Furthermore, even if the government had properly raised the argument, the HTSUS forecloses it. HTSUS heading 2936 explicitly encompasses “[p]rovitamins and vitamins” and “derivatives thereof used primarily as vitamins,” and Note 1(f) to Chapter 29 of the HTSUS expressly states that the headings of the chapter cover “[compounds] with an added stabilizer (including an anticaking agent) necessary for their preservation or transport.” HTSUS, Ch. 29, Note 1(f), at 29–1.

We thus agree with the CIT that Sigma-Tau's imported products, L-Tauro and GlycoCarn, should be viewed as equivalents of carnitine. The proper classification of carnitine itself determines the proper classification of Sigma-Tau's merchandise.

II

Chapter 29 of the HTSUS covers "Organic Chemicals." Heading 2936 more specifically covers "Provitamins and vitamins, natural or reproduced by synthesis (including natural concentrates), derivatives thereof used primarily as vitamins, and intermixtures of the foregoing, whether or not in any solvent." The terms "carnitine" and "vitamin Bt" do not appear anywhere under heading 2936 or, indeed, anywhere in Chapter 29. Thus, if carnitine is classifiable as a vitamin under heading 2936, it must be because it falls within a residual subheading, 2936.29.50 ("Vitamins and their derivatives, unmixed: Other vitamins and their derivatives: Other: Other").

The CIT construed HTSUS heading 2936 as, in relevant part, an *eo nomine* provision—i.e., a provision that describes an article by a specific name, not by use, *see Len-Ron Mfg. Co., Inc. v. United States*, 334 F.3d 1304, 1308 (Fed. Cir. 2003). *Sigma-Tau*, 98 F. Supp. 3d at 1376–77. We agree with the CIT that HTSUS heading 2936 should be treated as an *eo nomine* provision for purposes of this case: the operative question here is whether carnitine qualifies as a "[p]rovitamin[]” or “vitamin[],” items that are expressly named and covered by HTSUS heading 2936.³ Neither party disputes this interpretation. Because we conclude that HTSUS head-

³ HTSUS heading 2936 also encompasses “derivatives [of provitamins and vitamins] used primarily as vitamins”; this separate portion of heading 2936 is properly read as a use provision.

ing 2936 is an *eo nomine* provision with respect to “vitamins,” we need not consider the *Carborundum* factors, which pertain only to certain use provisions of the HTSUS. *See Aromont USA, Inc. v. United States*, 671 F.3d 1310, 1312–13 (Fed. Cir. 2012); *cf. GRK Canada, Ltd. v. United States*, 761 F.3d 1354, 1358 (Fed. Cir. 2014).

“The first step in properly construing a tariff classification term is to determine whether Congress clearly defined that term in either the HTSUS or its legislative history.” *Airflow Tech.*, 524 F.3d at 1290–91 (quoting *Russell Stadelman & Co. v. United States*, 242 F.3d 1044, 1048 (Fed. Cir. 2001)). In this instance, there is no clear definition of “vitamin” within Chapter 29 or its legislative history. We have held that,

[w]hen, as here, a tariff term is not defined in either the HTSUS or its legislative history, the term’s correct meaning is its common or dictionary meaning in the absence of evidence to the contrary. We have explained that, to determine the common meaning of a tariff term, a court may rely upon its own understanding of terms used, and may consult standard lexicographic and scientific authorities.

Id. at 1291 (citation, alterations, and internal quotation marks omitted). “To discern the common meaning of a tariff term, we may consult dictionaries, scientific authorities, and other reliable information sources.” *Kahrs Int’l, Inc. v. United States*, 713 F.3d 640, 644 (Fed. Cir. 2013). To the extent that dictionaries or other extrinsic references disagree with one another, a court may “properly rel[y] on the definition most commonly found in the lexicographical sources to derive the common meaning of this term.” *Len-Ron*, 334 F.3d at 1310.

Here the CIT’s decision that carnitine is *prima facie* classifiable as a vitamin rested on the fact that carnitine

is alternatively known as “vitamin Bt.” “[T]he Court finds that since L-Carnitine is commonly known as vitamin Bt it is *prima facie* classifiable in HTSUS heading 2936.” *Sigma-Tau*, 98 F. Supp. 3d at 1376. Similarly, the government argues in support of the opposite result that carnitine cannot be a vitamin because many respected scientific sources do not include carnitine in listings of commonly accepted vitamins. The government notes, for example, that a National Import Specialist for Customs testified with regard to Sigma-Tau’s carnitine products that “the FDA does not indicate they’re vitamins,” nor did the scientific literature he had reviewed. J.A. 750.

Whether a substance is commonly referred to as a “vitamin” may be pertinent, but only if there is a consensus as to the use of that terminology. *See Len-Ron*, 334 F.3d at 1310 (holding that the common meaning of the HTSUS term “vanity case” should not be limited to cases that include mirrors, as the record showed that the public uses the term to refer to a variety of cases, with no consensus that the term “requires that the case be fitted with a mirror”); *Nippon Kogaku (USA), Inc. v. United States*, 673 F.2d 380, 382, 384 (CCPA 1982) (holding that a certain type of optical microscope should be classified under a particular tariff heading because, *inter alia*, the CIT had found that “without contradiction, industry, as well as ophthalmologists and optometrists, principal users of the merchandise, refer to it as a slit-lamp microscope or a slit-lamp, not as a compound microscope”); *see also CamelBak Prods., LLC v. United States*, 649 F.3d 1361, 1368 (Fed. Cir. 2011) (holding that “how the subject articles are regarded in commerce” and “how the subject articles are described in sales and marketing literature” can “guide the court’s assessment of whether articles fall within the scope of an *eo nomine* provision”). There is no such consensus here. We must, therefore, determine whether carnitine is a “vitamin” under HTSUS heading

2936, applying the commonly accepted definition of the term “vitamin.”⁴

Indeed, HTSUS heading 2936 contemplates such an inquiry. By its very terms the heading covers not only approximately one dozen expressly named vitamins⁵ but also open-ended categories of further “Vitamins and their derivatives,” including “Other vitamins and their derivatives: Other: Aromatic or modified aromatic” (HTSUS subheading 2936.29.20) and “Other vitamins and their derivatives: Other: Other” (HTSUS subheading 2936.29.50). While Explanatory Notes to HTSUS headings are non-binding (*see infra*), the Explanatory Note to heading 2936 states in its “List of products which are to be classified as provitamins or vitamins within the mean-

⁴ This is not a case in which Customs or the importer contends that the term in question has a special commercial meaning distinct from its common meaning. See *Carl Zeiss, Inc. v. United States*, 195 F.3d 1375, 1379 (Fed. Cir. 1999) (“One who argues that a tariff term should not be given its common or dictionary meaning must prove that it has a different commercial meaning that is definite, uniform, and general throughout the trade.”); see also *Nix v. Hedden*, 149 U.S. 304, 306 (1893) (“There being no evidence that the words ‘fruit’ and ‘vegetables’ have acquired any special meaning in trade or commerce, they must receive their ordinary meaning.”)

⁵ The individual vitamins expressly included under HTSUS subheading 2936 are vitamin A (2936.21.00), vitamin B₁ (2936.22.00), vitamin B₂ (2936.23.00), D- or DL-pantothenic acid (vitamin B₃ or vitamin B₅, 2936.24.00), vitamin B₆ (2936.25.00), vitamin B₁₂ (2936.26.00), vitamin C (2936.27.00), vitamin E (2936.28.00), folic acid (2936.29.10), niacin and niacinamide (2936.29.15), vitamin D (2936.29.50.20), and biotin (2936.29.50.30).

ing of heading 29.36” that “[t]he list of products in each of the following groups is not exhaustive” and that “[t]he products listed are examples only.” Explanatory Notes to the Harmonized Commodity Description and Coding System 29.36 (5th ed. 2012) (“EN 29.36”). Explanatory Note 29.36 also includes a list of “Exclusions,” products “which, though sometimes called vitamins, have no vitamin activity or have a vitamin activity which is of secondary importance in relation to their other uses” and thus are not classifiable under HTSUS 2936. *Id.* Among the excluded products are various compounds whose names include the word “vitamin,” such as “Vitamin H₁,” “Vitamin B₄,” and “Vitamin F.” *Id.* (Carnitine (or vitamin Bt) is not included among the “Exclusions.” *Id.*) The note thus makes clear that the mere use of the term “vitamin” to refer to a particular compound is not conclusive. At the same time, the universe of compounds *prima facie* classifiable as vitamins under heading 2936 cannot be limited to only those compounds that are explicitly listed under the heading.

We thus look to the definition of “vitamin” and ask whether carnitine falls within the definition. “Determining the proper classification requires first construing the relevant provisions of the schedule and then deciding which provision encompasses the merchandise at issue.” *Del Monte Corp. v. United States*, 730 F.3d 1352, 1354 (Fed. Cir. 2013); *see also Airflow Tech.*, 524 F.3d at 1291. Before the CIT, the government urged that the court apply the definition of “vitamin” in the Explanatory Note:

Vitamins are active agents, usually of complex chemical composition, which are obtained from outside sources and are essential for the proper functioning of human or other animal organisms. They *cannot be synthesised by the human body* and must therefore be obtained in final or nearly final form (provitamins) from outside sources. They are effective in relatively minute amounts

and may be regarded as exogenous biocatalysts, their absence or deficiency giving rise to metabolic disturbances or “deficiency diseases.”

EN 29.36 (emphasis added). The government contended at the CIT that because carnitine can be synthesized in the human body, it is not a vitamin under the definition of EN 29.36. But Explanatory Notes are not Chapter Notes or Section Notes and are not binding. Explanatory Notes “may be generally useful as guides to the scope of unclear HTSUS headings, [but] they are not legally binding.” *Archer Daniels Midland Co. v. United States*, 561 F.3d 1308, 1315 (Fed. Cir. 2009) (internal quotation marks omitted); *see also E.T. Horn Co. v. United States*, 367 F.3d 1326, 1329 (Fed. Cir. 2004) (Explanatory Notes are “not controlling” but “provide interpretive guidance”). “Although the examples in the Explanatory Notes are probative and sometimes illuminating, we shall not employ their limiting characteristics, to the extent there are any, to narrow the language of the classification heading itself.” *Rubie’s Costume Co. v. United States*, 337 F.3d 1350, 1359 (Fed. Cir. 2003).

Explanatory Note 29.36, in defining vitamins as compounds that “cannot be synthesised by the human body,” cannot be correct, since vitamin D is unambiguously included under the heading: subheading 2936.29.50.20 expressly names “Vitamins D and their derivatives.” And undisputed evidence establishes that vitamin D can be synthesized, in limited and generally inadequate amounts, by the human body. *See Sigma-Tau*, 98 F. Supp. 3d at 1375–76. This portion of the definition of “vitamin” in EN 29.36 thus contradicts the express inclusion of vitamin D under HTSUS heading 2936 and must be disregarded, as the CIT correctly held. *Id.* at 1376. Explanatory Note 29.36 is also inconsistent with the prevailing definitions of “vitamin” in various scientific references cited by the parties, all of which define a vitamin as a compound that is not produced by the human

body in amounts “sufficient” or “adequate” for healthy function.⁶ The parties indeed agree that the definition of

⁶ The definitions of “vitamin” presented by the parties are as follows. Sigma-Tau’s expert submitted a report presenting definitions from two textbooks:

(From *The Vitamins*:) A vitamin: (i) is an *organic compound* distinct from fats, carbohydrates, and proteins; (ii) is a *natural component of foods* in which it is usually present in minute amounts; (iii) is essential, usually in minute amounts, for *normal physiological function* (i.e., maintenance, growth, development, and/or production); (iv) causes, by its absence or underutilization, a *specific deficiency syndrome*; and (v) is not synthesized by the host in amounts adequate to meet normal physiological needs.

(From *Nutrition Now*:) Vitamins are chemical substances that perform specific functions in the body. They are essential nutrients because, in general, the body cannot produce them or [cannot] produce sufficient amounts of them.

J.A. 288 (Expert Report of Yesu T. Das, quoting Gerald F. Combs, Jr., *The Vitamins* 4 (4th ed. 2012) (J.A. 291) and Judith E. Brown, *Nutrition Now* 20–2 (7th ed. 2014) (J.A. 292)) (alteration and emphasis in original, underscoring added).

The government introduced definitions from two chemical encyclopedias:

Vitamins are specific organic compounds that are essential for normal metabolism. *These micronutrients are not synthesized by humans, either at all or in sufficient quantity*, and must be obtained from the diet or as synthetic supplements.

EN 29.36 is too restrictive in this respect. For example, the government proposes defining “vitamins” as “those organic compounds which are essential for human health, but must be provided or supplemented from an exogenous source because the human body cannot normally synthesize the compounds, *either sufficiently or at all.*” Appellee’s Br. at 14 (emphasis added). Moreover, the definitions provided by both parties are consistent with each other. We therefore adopt, as the definition of “vitamin,” the following: vitamins are organic chemical substances that are essential micronutrients because, in general, the body cannot produce them or produce sufficient amounts of them.

While agreeing to this general definition, the parties still differ as to the proper scope of this definition in certain respects. First, Sigma-Tau argues that “vitamin” should not be limited to compounds that are required by individuals with normal function but should also encompass those required by individuals with abnormal function. We reject this argument. Literature definitions introduced by both parties emphasize the fact that a vitamin is a substance required for normal physiological

J.A. 778 (reproducing the *Concise Encyclopedia of Chem. Tech.* 2092 (4th ed. 1999)) (emphasis added).

Vitamins are essential, organic compounds *which are either not synthesized in the human and animal organism or formed only in insufficient amounts.* Therefore, they must be regularly consumed with the diet either as such or as a precursor (provitamin) that can be converted to the vitamin in the body. . . . Vitamins are classified not chemically but by their activity.

J.A. 780 (reproducing *Ullmann’s Encyclopedia of Indus. Chemistry* vol. 38, 112 (6th ed. 2003)) (emphasis added).

function. See J.A. 291 (*The Vitamins*: “essential . . . for *normal* physiological function”; “not synthesized by the host in amounts adequate to meet *normal* physiological needs” (emphasis added)); J.A. 292 (*Nutrition Now*: “essential nutrients because, *in general*, the body cannot produce them or produce sufficient amounts of them” (emphasis added)); J.A. 778 (*Concise Encyclopedia of Chem. Tech.*: “specific organic compounds that are essential for *normal* metabolism” (emphasis added)). The correct definition of “vitamin” thus leaves out compounds that might be essential to individuals with abnormal physiological function, e.g., those suffering from rare genetic disorders or organ failure.

Second, the government appears to argue that the proper definition of “vitamin” refers only to compounds that cannot be synthesized in sufficient amounts by human *adults*. On the contrary, Sigma-Tau argues that the proper definition of “vitamin” must not be limited to compounds essential to adults but should also include compounds that children and infants require for normal, healthy function. We agree with Sigma-Tau that there is no reason to limit “vitamin” to compounds required by adults rather than children. Neither the definition of EN 29.36 nor any of the literature definitions presented by either party is expressly limited to adults. Moreover, the definition in *The Vitamins* describes “vitamins” as compounds “essential” for “maintenance, *growth*, *development*, and/or production,” J.A. 291 (emphasis added); the inclusion of “growth” and “development” suggests that compounds required by children—i.e., those who are “growing” and “developing”—should be included even if not required by adults.

III

Having defined “vitamin,” we turn to whether carnitine is *prima facie* classifiable as such under HTSUS heading 2936. We hold, based on the undisputed evidence

of record, that the CIT's conclusion on this point was correct: carnitine is *prima facie* classifiable as a vitamin.

Sigma-Tau argues that the evidence shows that "certain human populations, including children and neonates, require an exogenous source of L-Carnitine." Appellant's Reply Br. at 14. Sigma-Tau introduced uncontroverted evidence establishing that infants, including neonates (infants less than four weeks old), require exogenous sources of carnitine for healthy growth and cannot synthesize adequate quantities endogenously. One scientific article states that "[n]eonates rely on an exogenous supply of L-carnitine because their capacity for endogenous synthesis is still poorly developed." J.A. 1089 (J. Harmeyer, *The Physiological Role of L-Carnitine*, 27 Lohmann Info. 1, 7 (2002)). A second article states that "certain pediatric populations, specifically neonates and infants, have decreased biosynthetic capacity and are at risk of developing carnitine deficiency, particularly when receiving PN [(parenteral nutrition)]" and that "[a]lthough carnitine is considered a nonessential nutrient in adults, it may be considered a conditionally essential nutrient in pediatric populations, particularly neonates receiving PN." J.A. 1091, 1094 (Catherine M. Crill & Richard A. Helms, *The Use of Carnitine in Pediatric Nutrition*, 22 Nutrition in Clinical Practice 204, 207 (2007)).

The scientific authorities cited by the government do not directly address the question of whether carnitine qualifies as a vitamin with respect to infants. They merely state that carnitine is not recognized as a vitamin in *adults*, as adults are able to synthesize adequate quantities of carnitine from other components of their diet. For example, the book *Recommended Dietary Allowances*, a publication of the National Research Council introduced by the government, states that "[carnitine] has not been demonstrated to be a vitamin for the healthy adult human" but adds that "the newborn infant appears to have

reduced stores of carnitine as well as a low capacity for synthesizing it” and that “[s]everal laboratories are investigating the possibility that carnitine may be an essential nutrient for the newborn, especially for those born prematurely.” J.A. 789, 790 (*Recommended Dietary Allowances* 265, 266 (10th ed. 1989)). At argument the government conceded that the evidence shows that infants, and neonates in particular, require exogenous sources of carnitine for normal, healthy function.

In view of this evidence, the CIT correctly held that carnitine is *prima facie* classifiable as a vitamin. Undisputed evidence in the record shows that carnitine is an organic compound essential for neonates (infants less than four weeks old). They rely on an exogenous supply of L-carnitine because their ability to synthesize it endogenously is still poorly developed.

CONCLUSION

For the foregoing reasons, carnitine and Sigma-Tau’s imported merchandise are *prima facie* classifiable as a vitamin under HTSUS heading 2936. As noted above, under Chapter Note 3, “[g]oods which could be included in two or more of the headings of this chapter are to be classified in that one of those headings which occurs last in numerical order.” We thus hold that carnitine, and Sigma-Tau’s products, are properly classified as a vitamin under HTSUS heading 2936, in residual subheading 2936.29.50, rather than as a quaternary ammonium salt under HTSUS heading 2923. We conclude that the CIT erred in denying Sigma-Tau’s motion for summary judgment and in granting summary judgment to the government. We reverse and remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED

COSTS

No costs.