Slip Op. 10-140

UNITED STATES COURT OF INTERNATIONAL TRADE

ROCHE VITAMINS, INC.,		
Plaintiff,		
	Before:	WALLACH, Judge
v.	Court No.:	04-00175
UNITED STATES,		
Defendant.		

[Plaintiff's Motion for Summary Judgment is DENIED.]

Dated: December 23, 2010

Grunfeld, Desiderio, Lebowitz, Silverman & Klestadt LLP (Erik D. Smithweiss, Robert B. Silverman, and Joseph M. Spraragen) for Plaintiff Roche Vitamins, Inc.

Tony West, Assistant Attorney General; Barbara S. Williams, Attorney in Charge, International Trade Field Office, Commercial Litigation Branch, Civil Division, U.S. Department of Justice (Saul Davis); and Sheryl A. French, Office of the Chief Counsel for Import Administration, U.S. Department of Commerce, Of Counsel, for Defendant United States.

OPINION

Wallach, Judge:

I
INTRODUCTION

This matter comes before the court on the Motion for Summary Judgment filed by Plaintiff Roche Vitamins, Inc. ("Roche") challenging the classification of merchandise by U.S. Customs and Border Protection ("Customs"). Jurisdiction exists pursuant to 28 U.S.C. § 1581(a). Because genuine issues of material fact affect the proper classification of Roche's imported merchandise, Roche's Motion for Summary Judgment is DENIED.

II
BACKGROUND

A
The Imported Merchandise

Beta-carotene is an organic colorant that has provitamin A activity. See Plaintiff's Statement of Material Facts Not In Dispute ("Roche's Facts") ¶¶ 8, 10, 32, 33; Defendant's Response to Plaintiff's Statement of Material Facts Not in Dispute ("Defendant's Factual Response")[1] ¶¶ 8, 10, 32, 33. Beta-carotene must be combined with other ingredients to be used as a colorant or provitamin A. See Roche's Facts ¶ 14; Defendant's Factual Response ¶ 14. As explained by Roche's expert, the imported merchandise sold under the trade name "BetaTab 20%" is a reddish brown/orange powder that "consists of 20% by weight synthetic beta-carotene crystalline." Memorandum of Law in Support of Plaintiff's Motion for Summary Judgment ("Roche's Motion") Att. 2: Declaration of Jean Claude Tritsch ("Tritsch Decl.") ¶¶ 8, 9.

> The individual particles of the powder contain a finely dispersed solution of beta carotene in a cornstarch-coated matrix of gelatin and sucrose. Antioxidants are also present in the particles. . . . BetaTab 20% is produced by dissolving beta carotene crystalline powder in a solvent along with [two additional, stabilizing antioxidants]. Separately, gelatin, sucrose, and [a third stabilizing antioxidant] are dissolved in the water. The two solutions are blended together to produce an emulsion after which the solvent is distilled from the emulsion. The emulsion is then sprayed as droplets into corn starch. The resulting particles are dried, freed from excess corn starch and filled into containers. The particles are in the shape of microspheres, and are referred to as beadlets.

Id. ¶¶ 9, 10, 11.

[1] Roche devotes much of its reply brief arguing that numerous statements in Roche's Facts should be "deemed admitted" pursuant to USCIT R. 56(h)(3) based on non-admissions contained in Defendant's Factual Response. See Plaintiff's Memorandum of Law in Reply to Defendant's Opposition to Plaintiff's Motion for Summary Judgment ("Roche's Reply") at 10-15. Two such non-admissions appear devoid of the requisite "citation to evidence which would be admissible." USCIT R. 56(h)(4); see Roche's Reply at 13; Defendant's Factual Response ¶¶ 22, 23. For the remaining challenged non-admissions, Roche argues that Defendant's supporting evidence is inadequate. See Roche's Reply at 12-15; Defendant's Factual Response ¶¶ 15-17, 21, 25, 26, 29, 36. The court will not order any statements "deemed admitted" on the basis of argument in a reply brief; Roche may, if appropriate, file a motion seeking relief. See USCIT RR. 7(b), 37.

"BetaTab 20% was developed, designed, and marketed as a source of beta-carotene for purposes of sale to makers of dietary supplements (tablets and capsules) who seek a high beta-carotene/provitamin A content and antioxidant activity." Plaintiff's Response to Defendant's Statement of Material Facts as to Which There Is No Genuine Dispute ("Roche's Factual Response") ¶ 7; Defendant's Statement of Material Facts as to Which There Is No Genuine Dispute ("Defendant's Facts") ¶ 7. "The Roche marketing materials for BetaTab 20% do not mention any intent or use . . . as a food colorant. . . . Any colorant function in the actual use of BetaTab 20% is unintentional or ancillary." Defendant's Facts ¶ 8; Roche's Factual Response ¶ 8.

B
The Classification By Customs And This Litigation

BetaTab 20% was imported into the United States by Roche in December 2002 alongside another Roche product, "B-Carotene 7% CWS." Roche's Facts ¶¶ 1-3; Defendant's Factual Response ¶¶ 1-3. The CWS ("cold water soluble") designation does not apply to BetaTab 20% because it will normally disperse only in a heated solution. See Tritsch Decl. ¶ 16; Defendant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ("Defendant's Opposition") at 7. Customs classified BetaTab 20% under subheading 2106.90.97 of the Harmonized Tariff Schedule of the United States ("HTSUS") and assessed duties at the rate of 8.5% ad valorem plus 28.8 cents per kilogram. See Summons (April 23, 2004).

Roche filed a protest in March 2004 that was denied by Customs in April 2004. See id. Roche thereafter initiated this case. See Complaint (September 2, 2004). Roche alleged that both products should be classified under HTSUS subheading 3204.19.35 (normally dutiable at 3.1% ad valorem), id. ¶ 13, and eligible for duty-free entry pursuant to the HTSUS Pharmaceutical Appendix ("PA"), id. ¶ 16, or, alternatively, classified as duty-free under HTSUS Heading 2936,

id. ¶ 19.[2] In 2009, Roche and Defendant United States ("Defendant") stipulated that B-Carotene 7% CWS "is classifiable . . . under subheading 3204.19.35, HTSUS (2002)" and "request[ed] that when final judgment in this action is entered, reliquidation be ordered . . . according[ly]." November 13, 2009 Stipulation ¶¶ 3, 5.[3]

Roche now moves for summary judgment. See Roche's Motion. Defendant contends that the classification of BetaTab 20% under HTSUS subheading 2106.90.97 was proper, see Defendant's Opposition at 1-3, but if classification is found under Heading 3204, "then the merchandise is properly classifiable in subheading [3204.19.50], HTSUS, at a duty rate of [7.8%] ad valorem." Answer (November 15, 2004) ¶ 22; see Defendant's Opposition at 9.

HTSUS Headings 2106, 2936, and 3204 and the relevant subheadings provide as follows:

2106	Food preparations not elsewhere specified or included:
. . . .	
2106.90	Other: . . . .
. . . .	
2106.90.97	Other: . . . .
. . . .	
2936	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:
2936.10	Provitamins, unmixed
. . . .	

[2] Although Roche initially sought, in the alternative, classification under HTSUS subheadings 2936.10.00 or 2936.90.00, see Complaint ¶ 19, Roche now seeks summary judgment for classification under HTSUS Chapter 29 pursuant only to subheading 2936.10.00. See Roche's Motion at 23-30; Defendant's Memorandum in Opposition to Plaintiff's Motion for Summary Judgment at 2 n.2 ("Defendant's Opposition"). Roche has not abandoned its claim under subheading 2936.90.00. See July 29, 2010 Oral Argument at 3:00-4:35.

[3] Roche compares BetaTab 20% with B-Carotene 7% CWS to demonstrate that HTSUS subheading 3204.19.35 is the proper classification for both. See Roche's Motion at 3-4, 10-12. Argument based upon comparison between these products is premature because: B-Carotene 7% CWS has not yet been classified; the proper classification of merchandise is ultimately a question of law; and the court has an independent duty to reach the correct result in classification cases. See November 13, 2009 Stipulation; Bausch & Lomb, Inc. v. United States, 148 F.3d 1363, 1366 (Fed. Cir. 1998); Jarvis Clark Co. v. United States, 733 F.2d 873, 878 (Fed. Cir. 1984). Moreover, as Defendant informed the court at oral argument, B-Carotene 7% CWS is made for use as a colorant, in contrast to BetaTab 20%. See July 29, 2010 Oral Argument at 15:23-16:16.

3204	Synthetic organic coloring matter, whether or not chemically defined; preparations as specified in note 3 to this chapter based on synthetic coloring matter;		
3204.19		Other, including mixtures of coloring matter of two or more of the subheadings 3204.11 to 3204.19:	
3204.19.35			Beta-carotene and other carotenoid coloring matter
. . . .			
		Other:	
3204.19.40			Products described in additional U.S. note 3 to section VI
. . .			
3204.19.50			Other
. . . .			

Heading 2106, HTSUS (2002); Heading 2946, HTSUS (2002); Heading 3204, HTSUS (2002).

The HTSUS provides that certain imported products are eligible for duty-free entry pursuant to the PA. "Whenever a rate of duty of 'Free' followed by the symbol 'K' in parentheses appears in the 'Special' subcolumn for a heading or subheading, any product (by whatever name known) . . . shall be entered free of duty, provided that such product is included in the [PA]." Gen. Note 13, HTSUS (2002) (emphasis in original). The PA identifies "BETACAROTENE," [Chemical Abstracts Service Registry number] "7235-40-07." Pharmaceutical Appendix, HTSUS (2002), Table 1. Subheading 3204.19.35 includes the following special rate of duty: "Free (. . . K . . .)." Subheading 3204.19.35, HTSUS (2002).

III
STANDARD OF DETERMINATION

In a classification case, "the court construes the relevant (competing) classification headings, a question of law; determines what the merchandise at issue is, a question of fact; and then" determines "the proper classification under which [the merchandise] falls, 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).

The court will grant a motion for summary judgment "if the pleadings, discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." USCIT R. 56(c); see Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). On a motion for summary judgment, this court "may not resolve or try factual issues." Phone-Mate, Inc. v. United States, 12 CIT 575, 577 (1988), aff'd, 867 F.2d 1404 (Fed. Cir. 1989) (citation omitted). Accordingly, summary judgment in a classification case is appropriate only if "the material facts of what the merchandise is and what it does are not at issue." Diachem Indus. Ltd. v. United States, 22 CIT 889, 892 (1998) (citation omitted).

The court determines the proper classification de novo by applying the HTSUS General Rules of Interpretation ("GRIs") in numerical order, as well as the HTSUS Additional Rules of Interpretation ("ARI"). See Faus Group, Inc. v. United States, 581 F.3d 1369, 1372 (Fed. Cir. 2009); Carl Zeiss, Inc. v. United States, 195 F.3d 1375, 1379 (Fed. Cir. 1999); Rollerblade, Inc. v. United States, 112 F.3d 481, 483-84 (Fed. Cir. 1997). The GRI 1 starting point provides in relevant part that, "for legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes." GRI 1, HTSUS (2002).

"Absent contrary legislative intent, HTSUS terms are to be construed according to their common and commercial meanings, which are presumed to be the same." Carl Zeiss, 195 F.3d at 1379 (citing Simod Am. Corp. v. United States, 872 F.2d 1572, 1576 (Fed. Cir. 1989)). "To assist it in ascertaining the common meaning of a tariff term, the court may rely on its own understanding of the terms used and may consult lexicographic and scientific authorities,

dictionaries, and other reliable information sources." Baxter Healthcare Corp. v. United States, 182 F.3d 1333, 1337-38 (Fed. Cir. 1999) (citation omitted). Although not dispositive, the Explanatory Notes ("EN") maintained by the Harmonized System Committee of the World Customs Organization "clarify the scope of the HTSUS subheadings and offer guidance in their interpretation." Franklin v. United States, 289 F.3d 753, 758 (Fed. Cir. 2002) (citation omitted); see H.R. Conf. Rep. No. 100-576, 100th Cong., 2d Sess. 549 (1988) at 26-27, reprinted in 1988 U.S.C.C.A.N. 1547, 1582.

Classification decisions made by Customs may be entitled to some weight in accordance with Skidmore v. Swift & Co., 323 U.S. 134, 65 S. Ct. 161, 89 L. Ed. 124 (1944). Under Skidmore, "an agency's interpretation may merit some deference . . . given the 'specialized experience and broader investigations and information' available to the agency." Mead Corp., 533 U.S. 218, 234, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001) (quoting Skidmore, 323 U.S. at 139). The amount of respect afforded "will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." Skidmore, 323 U.S. at 140.[4]

IV
DISCUSSION

Roche's Motion for classification under HTSUS subheading 3204.19.35 is denied. Infra, Part IV.A. According to applicable precedent, infra Part IV.A.1, the Heading 3204 term "coloring matter" is a principal use provision in this action, infra Part IV.A.2. Genuine issues of

[4] Defendant does not here seek deference for the denial of Roche's protest that only references Customs determinations for beta-carotene products other than BetaTab 20%. See U.S. Customs and Border Protection, Protest No. 1101-04-100088 (April 6, 2004); Defendant's Opposition at 1-28.

material fact remain as to whether BetaTab 20% belongs to the class or kind of goods principally used as coloring matter. Infra, Part IV.A.3. Roche's Motion for duty-free eligibility under the PA and Defendant's requested alternate classification under subheading 3204.19.50 need not be resolved at this stage because they both depend upon the classification of BetaTab 20% under Heading 3204. Infra, Part IV.A.4. Roche is also not entitled to summary judgment for classification under HTSUS Heading 2936 because a genuine issue remains as to the functionality of the BetaTab 20% ingredients. Infra, Part IV.B.

A.
Summary Judgment Is Not Appropriate To Classify BetaTab 20% Under Heading 3204

1.
Precedent Interpreting The Heading 3204 Term "Coloring Matter"

(a)
E.M. Chems. v. United States

This court has previously held that "the term 'coloring matter' in Heading 3204 is a principal use provision." E.M. Chems. v. United States, 20 CIT 382, 386, 923 F. Supp. 202 (1996) (denying summary judgment because of conflicting evidence as to the principal use of thermochromic liquid crystals). "The word 'coloring' acts as an adjective modifying the word 'matter' in a way that compels one to consider some aspect of use." Id. (internal quotations omitted). Federal Circuit precedent supported the principal use determination in E.M. Chems. Id. at 387 (citing Stewart-Warner Corp. v. United States, 748 F.2d 663, 667 (Fed. Cir. 1984) (provision for "bicycle speedometers" controlled by "chief use" because "'bicycle' [modifies] 'speedometer' in a way that implies use of the speedometer on a bicycle")). EN 32.04 also supported Heading 3204 being a principal use provision by stating "explicitly that 'substances which in practice are not used for their dying properties are **excluded**.' . . . A list of substances

that are used for purposes other than coloring are excluded from the 'coloring matter' heading." Id. at 387 (citations omitted) (bolded emphasis in original and underlined emphasis added).

This principal use designation triggers application of ARI 1(a) in the Heading 3204 classification analysis. Id. ARI 1 provides in relevant part as follows:

> In the absence of special language or context which otherwise requires--(a) 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 . . . .

ARI 1, HTSUS (2002).

In the "principal use" analysis, the court "must ascertain the class or kind of goods which are involved and decide whether the subject merchandise is a member of that class." E.M. Chems., 20 CIT at 388. "The purpose of 'principal use' provisions in the HTSUS is to classify particular merchandise according to the ordinary use of such merchandise, even though particular imported goods may be put to some atypical use." Primal Lite, Inc. v. United States, 182 F.3d 1362, 1364 (Fed. Cir. 1999) (emphasis added). The Federal Circuit describes ARI 1(a) as "call[ing] for a determination as to the group of goods that are commercially fungible with the imported goods." Id. at 1365. Traditionally, courts undertaking the principal use analysis examine multiple factors that include:

(1) the general physical characteristics of the merchandise;
(2) the expectation of the ultimate purchasers;
(3) the channels of trade in which the merchandise moves;
the environment of the sale (e.g. the manner in which the merchandise is advertised and displayed);
(4) the usage of the merchandise;
(5) the economic practicality of so using the import; and
(6) the recognition in the trade of this use.

E.M. Chems., 20 CIT at 388 (citing United States v. Carborundum Co., 63 CCPA 98, 102, 536 F.2d 373 (1976) (subsequent history omitted)).

(b)
BASF v. United States

After E.M. Chems., this court conducted a trial to classify a beta-carotene product. See BASF Corp. v. United States, 29 CIT 681, 684, 391 F. Supp. 2d 1246 (2005) ("BASF I"), aff'd, BASF Corp. v. United States, 482 F.3d 1324 (Fed. Cir. 2007) ("BASF II"). The parties agreed that Lucarotin® 1% should be classified under HTSUS Heading 3204. See BASF I, 29 CIT at 682. This court classified Lucarotin® 1% under subheading 3204.19.35, as opposed to subsequent subheadings that cover "[o]ther." Subheading 3204.19.40, HTSUS (2002); subheading 3204.19.50, HTSUS (2002); see BASF I, 29 CIT at 681-82. This classification was affirmed by the Federal Circuit. See BASF II, 482 F.3d at 1326-27. Besides the 19 percentage-point difference in beta-carotene concentration, the following findings of fact from the BASF I trial distinguish Lucarotin® 1% from BetaTab 20%:

- "Lucarotin® 1% . . . is sold for use as a food colorant," BASF I, 29 CIT at 684;
- "Lucarotin® 1% . . . is used to impart color to a wide variety of foods," id.;
- "Customers do not buy Lucarotin® 1% for any purpose other than delivery of a beta-carotene colorant," id.; and
- "Lucarotin® 1% is marketed . . . for coloration," id. at 687.

In classifying Lucarotin® 1%, both this court and the Federal Circuit emphasized the product's purpose and intent. This court concluded that "inclusion of the term 'matter' . . . clearly contemplates that products within the scope of the subheading would be beta-carotene or other carotenoid colorants of a particular kind or for a particular purpose." Id. at 691. In affirming, the Federal Circuit explained "that this product is not intended for vitamin or other pharmaceutical use, but is intended for use as a food colorant." BASF II, 482 F.3d at 1326. The Federal Circuit further affirmed this court's determination that Lucarotin® 1% was not eligible for duty-free entry under the PA. See BASF I, 29 CIT at 692 n.7; BASF II, 482 F.3d at 1327.

2.

The Heading 3204 Term "Coloring Matter" Is A Principal Use Provision In This Action

Roche disputes the applicability of the E.M. Chems. holding that "the term 'coloring matter' in Heading 3204 is a principal use provision." E.M. Chems., 20 CIT at 386; see Plaintiff's Supplemental Brief Pursuant to the Court's August 13, 2010 Order ("Roche's Supp. Brief") at 1-3. According to Roche, ARI 1(a) does not apply to the classification of BetaTab 20% because "of special language or context which otherwise requires." Roche's Supp. Brief at 3 (quoting ARI 1, HTSUS (2002)). In support of this argument, Roche cites subheading 3204.19.35, Chapter 29 Note 2(f), certain ENs, and the PA. See id. None of these, however, constitute "special language or context . . . ." ARI 1, HTSUS (2002)

Roche first emphasizes that "beta carotene is eo nomine provided for in subheading 3204.19.35." Roche's Supp. Brief at 3. However, a subheading term cannot be read into a heading term from which it is absent. See JVC Co. of Am. v. United States, 234 F.3d 1348, 1352 (Fed. Cir. 2000) ("Only after determining that a product is classifiable under a particular heading should the court look to the subheadings to find the proper classification") (citation omitted). The subheading term "beta carotene" is therefore not "special language or context" rendering ARI 1(a) inapplicable to whether BetaTab 20% is encompassed by the term "[s]ynthetic organic coloring matter." Subheading 3204.19.35, HTSUS (2002); ARI 1, HTSUS (2002); Heading 3204, HTSUS (2002).

Roche next seeks support for its position from HTSUS Chapter 29 Note 2(f). See Roche's Supp. Brief at 3. That note provides that Chapter 29 "does not cover . . . synthetic organic coloring matter . . . (heading 3204)." Ch. 29 n.2(f), HTSUS (2002). According to Roche, this note requires that any beta-carotene product "must be classified in heading 3204, regardless of its use for its provitamin A properties . . . But for Note 2(f) to Chapter 29, beta-carotene would

be classifiable under heading 2936 since it is provitamin A." Roche's Motion at 16, 19. However, this note does not preclude certain beta-carotene products from classification under, inter alia, Heading 2936, see infra Part IV.B, or a catchall HTSUS provision such as that used by Customs to classify BetaTab 20%, see Defendant's Opposition at 1-2. Note 2(f) only cross-references the term "coloring matter," which this court and the Federal Circuit have construed with an emphasis on the intended use and use of a product as coloring matter. See BASF I, 29 CIT at 691; BASF II, 482 F.3d at 1326-27.[5] Chapter 29 Note 2(f) is therefore not "special language or context" rendering ARI 1(a) inapplicable. ARI 1, HTSUS (2002).

Roche also misplaces reliance on the ENs. EN 32.04 provides that: "Substances which in practice are not used for their dyeing properties are **excluded**." EN 32.04(I) (bolded emphasis in original and underlined emphasis added);[6] see supra Part IV.A.1(a) (discussing the role of EN 32.04 in E.M. Chems., 20 CIT at 387). The EN to Heading 2936 "**excludes**: . . . Provitamins A (α-, β- and γ-carotenes . . .) because of their use as colouring substances." EN 29.36 (bolded emphasis in original and underlined emphasis added). Roche argues that "the ENs reflect the fact that provitamins A (including beta-carotene) are inherently dual use (provitamin activity and coloring) products and the drafters of the tariff determined that beta-carotene is to be classified in heading 3204 regardless of whether it is being used for its provitamin A properties or for its

[5] Although these BASF statements were made in the context of HTSUS subheading 3204.19.35, they apply to Heading 3204 because of the common "coloring matter" language. Heading 3204, HTSUS (2002); subheading 3204.19.35, HTSUS (2002).

[6] The list of examples that accompanies this EN exclusion does not include beta-carotene, but envisions additional substances by stating "e.g." before the examples. EN 32.04(I). This EN does expressly include "carotenoids obtained by synthesis (e.g., β-carotene)." EN 32.04(I)(E)(15). Roche relies on this inclusion. See Roche's Motion at 13; Roche's Reply at 3. However, such a general reference only illustrates that beta-carotene substances may be encompassed in HTSUS Heading 3204, as recognized by this court and the Federal Circuit. See BASF I, 29 CIT 681, 688; BASF II, 482 F.3d 1324, 1328. The EN reference to beta-carotene does not suggest all substances containing beta-carotene are to be classified under Heading 3204, particularly given the EN exclusion for substances not used as colorants. See EN 32.04(I).

coloring properties." Roche's Reply at 3. However, that both EN exclusions expressly employ the word "use" refutes the position that beta-carotene products must be classified under Heading 3204 without concern for their usage. EN 29.36; EN 32.04(I). The ENs are therefore not "special language or context" rendering ARI 1(a) inapplicable to the classification of BetaTab 20%. ARI 1, HTSUS (2002).

Roche finally argues that the principal use framework does not apply because merchandise classified under subheading 3204.19.35 is eligible for duty-free entry under the PA. The K designation was added to subheading 3204.19.35 subsequent to the entries at issue in E.M. Chems. See E.M. Chems., 20 CIT at 385 n.3; compare subheading 3204.19.35, HTSUS (1994) with subheading 3204.19.35, HTSUS (1995). According to Roche:

> the "K" indicator in the special duty column is a clear indication of Congressional intent that beta-carotene products classified in subheading 3204.19.35 are eligible for duty free entry under [the PA]. If beta-carotene mixtures principally used as provitamins are not classifiable in subheading 3204.19.35, then the [PA] would not apply to any commercial beta-carotene products.

Roche's Supp. Brief at 3.

The K designation is insufficient for this court to disregard its previous holding that "the term 'coloring matter' in Heading 3204 is a principal use provision." E.M. Chems., 20 CIT at 387. That determination was based on Heading 3204's language, Federal Circuit precedent, and EN 32.04. See id. at 386-87. Moreover, merchandise that belongs to a class or kind principally used as coloring matter could conceivably be eligible for duty-free entry under the PA, as Lucarotin® 1% in BASF was sold, used, and marketed as a colorant.[7] See BASF I, 29 CIT at 684, 687. In denying duty-free entry, the Federal Circuit noted that Lucarotin® 1% was "not

[7] As Defendant notes, although "the two BASF decisions did not discuss 'principal use,' as prescribed by ARI 1(a), that may very well be due to the fact that there was no dispute that the Lucarotin in that case was principally used, if not solely used[,] as a colorant, and belonged to a class that was principally used as colorants." Defendant's Supp. Brief at 2 n.3.

imported as a vitamin product." BASF II, 482 F.3d at 1327 n.3. Vitamins belonging to a class or kind of goods principally used as coloring matter could accordingly be classified under Heading 3204 and eligible for duty-free entry. See infra, Part IV.A.4. The K designation is therefore not "special language or context" rendering ARI 1(a) inapplicable to the classification of BetaTab 20%. ARI 1, HTSUS (2002).

3.
Genuine Issues Of Material Fact Affect Whether BetaTab 20% Belongs To A Class Or Kind Of Goods Principally Used As "Coloring Matter"

The principal use inquiry requires a determination of the "class or kind of goods to which" BetaTab 20% belongs. ARI 1(a), HTSUS (2002). Roche emphasizes "that beta-carotene, as a class of merchandise, is principally used as a colorant." Roche's Supp. Brief at 2 (citing BASF I, 29 CIT at 685). Defendant counters that BetaTab 20% "fits within a class or kind of goods principally used as ingredients in dietary supplements." Defendant's Supp. Brief at 5. In determining whether BetaTab 20% is "commercially fungible" with either beta-carotene coloring matter or ingredients for dietary supplements, this court will consider multiple factors. Primal Lite, 182 F.3d at 1365; see E.M. Chems., 20 CIT at 388 (citing Carborundum, 63 CCPA at 102).

The "general physical characteristics" factor appears to support Roche based on the undisputed fact that BetaTab 20% "can be used as a colorant." E.M. Chems., 20 CIT at 388 (citing Carborundum, 63 CCPA at 102); Roche's Facts ¶ 33; Defendant's Factual Response ¶ 33. Defendant's expert testified that BetaTab 20% "could be accurately described as beta-carotene coloring matter" and Defendant concedes that BetaTab 20% is "similar to some products used [as] colorants." Roche's Reply Ex. A: Deposition of Mitchell Russell, M.D., at 63:12-14; Defendant's Supp. Brief at 4. However, BetaTab 20%'s beadlet form may distinguish this merchandise from a class or kind of goods principally used as coloring matter. See Tritsch Decl.

Ex. 4 at 3 (listing multiple Roche beta-carotene products and identifying the "Main Application" of the only "beadlet" product "[a]s a non-coloring nutrient for dry food preparations.").

Other factors appear to support Defendant, particularly "the manner in which the merchandise is advertised" and "the usage of the merchandise" given the lack of dispute over the "marketing materials" and "actual use of BetaTab 20%." E.M. Chems., 20 CIT at 388 (citing Carborundum, 63 CCPA at 102); Defendant's Facts ¶ 8; Roche's Factual Response ¶ 8; see Defendant's Supp. Brief at 4-5. Despite these indicators from the record, the parties have not satisfactorily applied the principal use factors to the classification of BetaTab 20%.[8] Roche only requests that if ARI 1(a) is found applicable, the court "afford[] plaintiff 60 days to either abandon or supplement its motion for summary judgment for classification in K3204.19.35 with additional facts and arguments relevant to the Carborundum factors." Roche's Supp. Brief at 5; see Roche's Motion; Roche's Reply; Roche's Supp. Brief. Defendant addresses the factors in a perfunctory fashion without record support. See Defendant's Supp. Brief at 4-5; Defendant's Opposition. At this stage, and as in E.M. Chems., that material facts remain in dispute concerning the principal use analysis precludes summary judgment for classification under HTSUS Heading 3204. See E.M. Chems., 20 CIT at 384.

Roche's Motion cannot be granted because of outstanding genuine issues of material fact as to whether BetaTab 20% belongs to the class or kind of goods principally used as coloring matter. See ARI 1(a), HTSUS (2002). Either party may move to re-open discovery for the limited purpose of classifying BetaTab 20% under Heading 3204 pursuant to ARI 1(a). After this new discovery period, Roche may move for summary judgment to classify BetaTab 20%

[8] The parties only addressed the E.M. Chems. principal use issue in response to questions at oral argument and a court order for supplemental briefing. See July 29, 2010 Oral Argument at 7:50-10:05; 27:48-28:03; August 13, 2010 Order.

under Heading 3204 and Defendant may move for partial summary judgment to establish that BetaTab 20% is not classified under Heading 3204. If an appropriate motion is not filed within 15 days of the date of this Opinion, a trial will be scheduled in this action.

4.
The Remaining Heading 3204 Arguments Need Not Be Resolved At This Stage

Roche's claim for duty-free entry under the PA and Defendant's requested alternate classification under HTSUS subheading 3204.19.50 both depend on BetaTab 20% first being classified under Heading 3204. See Defendant's Opposition at 9; Plaintiff's Motion at 18. Unless and until BetaTab 20% is classified under Heading 3204, these issues need not be resolved. Roche's PA arguments will nevertheless be briefly addressed to provide guidance in the event that BetaTab 20% is classified under subheading 3204.19.35. This court in BASF I concluded that "Lucarotin® 1% is not 'used in the prevention, diagnosis, alleviation, treatment, or cure of disease in humans or animals,' which the [U.S. International Trade Commission ('ITC')] identifies as a pharmaceutical or 'drug.' Lucarotin® 1% is thus not eligible for duty-free treatment under the [PA]." BASF I, 29 CIT at 692 n.7 (quoting Advice Concerning the Addition of Certain Pharmaceutical Products and Chemical Intermediates to the [PA], ITC Pub. 3167, at 3 (April 1999)).

A preliminary issue is whether BetaTab 20% satisfies this BASF I standard. The "proven benefit of beta-carotene in terms of human health . . . as a source of vitamin A" supports the conclusion that BetaTab 20% is "used in the prevention, diagnosis, alleviation, treatment, or cure of diseases in humans." Defendant's Facts ¶ 5; Roche's Factual Response ¶ 5; BASF I, 29 CIT at 692. The record does not support Defendant's assertion that BetaTab 20% is simply a nutritional supplement devoid of use for therapeutic or prophylactic purposes. See Defendant's Opposition at 21; July 29, 2010 Oral Argument at 16:30-19:16. The vitamin A benefit favors BetaTab 20%

being eligible for duty-free entry in the event that it is classified under subheading 3204.19.35, even if the beneficial health impacts of antioxidants are "a matter of scientific debate." Roche's Factual Response ¶ 5.

More fundamentally, Roche challenges the applicability of the BASF I standard to the classification of vitamins. In arguing that beta-carotene vitamins are entitled to duty-free entry under the PA regardless of use as a drug, Roche asks this court to revisit its BASF I conclusion. See Roche's Motion at 22-23; Roche's Reply at 5-6. The Federal Circuit, in affirming this court's denial of duty-free eligibility under the PA, "note[d] the concern of the amici curae [Roche et al.] that if this formulation is denied access to the [PA], other beta-carotene products may be wrongly classified. That concern is unfounded, for Lucarotin® 1% is unambiguously not imported as a vitamin product." BASF II, 482 F.3d at 1327 n.3. Roche relies upon this footnote to support the proposition that the Federal Circuit "strongly intimated that a beta-carotene product that was imported as a vitamin product could qualify as a listed product." Roche's Motion at 23.[9]

BASF II suggests that the PA may apply to some products that do not satisfy ITC's definition of "pharmaceutical or 'drug.'" BASF I, 29 CIT at 692 n.7 (citation omitted). The Federal Circuit, in affirming that Lucarotin® 1% is not eligible for duty-free entry, indicated that its holding may not apply to vitamins. See BASF II, 482 F. 3d at 1326, 1327 n.3. In addition to the footnote addressing Roche, the Federal Circuit emphasized that the "product is not intended

[9] Roche further relies upon Customs determinations for support that all beta-carotene vitamins receive duty-free treatment under the PA when classified under an eligible subheading. See Roche's Reply at 5-6 (citing Customs Ruling No. NY B84625 (April 29, 1997) ("NY B84625") (granting PA duty-free treatment for beta-carotene crystalline, "a widely used carotenoid in the food industry"); Customs Headquarters Determination No. 963030 (October 23, 2000) ("HQ 963030") (finding that "[a] product need not be considered a 'drug' in order to be included in the [PA]."). Because these determinations pre-date BASF I and contain only scant analysis, they lack "power to persuade" with respect to the viability of the BASF I standard after BASF II. Skidmore, 323 U.S. at 140; see NY B84625; HQ 963030.

for vitamin or other pharmaceutical use." Id. at 1326. Therefore, in the event that BetaTab 20% is classified under subheading 3204.19.35, the standard for PA eligibility may differ from the question of whether ITC would recognize the product "as a pharmaceutical or 'drug.'" BASF I, 29 CIT at 692 (citation omitted).

B.
Summary Judgment Is Not Appropriate To Classify BetaTab 20% Under Heading 2936

Roche in the alternative moves for summary judgment to classify BetaTab 20% as "[p]rovitamins and vitamins, natural or reproduced by synthesis . . . whether or not in any solvent." Heading 2936, HTSUS (2002); see Roche's Motion at 23-30. HTSUS Chapter 29 Note 1 establishes that Chapter 29 covers basic chemicals accompanied only by limited additions. See Ch. 29 n.1, HTSUS (2002). Note 1(f) specifies as permissible the addition of a "stabilizer (including an anticaking agent) necessary for . . . preservation or transport." Id. at n.1(f). A "stabilizer" is defined as "[a]ny substance that tends to maintain the physical and chemical properties of a material." McGraw-Hill Dictionary of Scientific and Technical Terms 2011 (6th Ed. 2002).

> General EN 29.36(d) provides guidance on the acceptable stabilizers as follows:
>
> The products of . . . heading [2936] may be stabilised for the purposes of preservation or transport :
> - by adding anti-oxidants,
> - by adding anti-caking agents . . . ,
> - by coating with appropriate substance (e.g., gelatin . . .), whether or not plasticised, . . .
>
> **provided** that the quantity added . . . in no case exceeds that necessary for their preservation or transport and that the addition . . . does not alter the character of the basic product and render it particularly suitable for specific use rather than for general use.

Gen. EN 29.36(d) (bolded emphasis in original and underlined emphasis added).[10]

Roche contends that the BetaTab 20% qualifies under HTSUS 29 Chapter Note 1(f) because the ingredients beyond beta-carotene are mere stabilizers. See Roche's Motion at 25-27. It is undisputed that BetaTab 20% is produced by mixing synthetic beta-carotene crystals with stabilizing ingredients. See Roche's Facts ¶ 15; Defendant's Factual Response ¶ 15. "[T]he corn starch acts as an anti-caking agent to maintain particle separation during the manufacture of the beadlet." Tritsch Decl. ¶ 32. Beta-carotene is susceptible to oxidation, which "destroys its provitamin A activity and coloration properties." Id. ¶ 7. Defendant agrees that the antioxidants serve a stabilizing function, the gelatin and sucrose protect beta-carotene molecules against oxidation and water vapor, and the sucrose additionally provides for mechanical stability. See Roche's Facts ¶¶ 25, 28; Defendant's Factual Response ¶¶ 25, 28.

Defendant argues, however, that these BetaTab 20% ingredients accomplish significantly more than stabilization. See Defendant's Opposition at 25-26. Defendant's expert opines:

> The sucrose and gelatin are not simply components of a stabilizing matrix. . . . [T]he sucrose was added to the preparations for use in making tablets precisely because the sucrose acts as a plasticizer and provides mechanical strength during the tableting process. The gelatin acts as an important emulsifier that assists in providing efficient dispersion of the beta-carotene for greater bioavailability to the body. Thus, the matrix is not simply a stabilizing agent. The components act as adjuvants – they are added to the beta-carotene to either effectuate the manufacture of the beadlets, to effectuate the use of the beta-carotene in the production of multi-vitamin and other nutritional supplements, to increase the

[10] Defendant relies upon the General EN to Chapter 28 that contains the identical "**provi[sion]**" and is incorporated by reference as "apply[ing] mutatis mutandis" by a General EN to Chapter 29. Defendant's Opposition at 24 (citing Ch. 28 Gen. EN (A); Ch. 29 Gen EN (A)) (emphasis in original). Roche replies that the Chapter 29 EN allowance for plasticized gelatin "takes precedence" over the General EN to Chapter 28 and thereby requires a "necessary change" pursuant to the "mutatis mutandis" qualifier. Roche's Reply at 8. However, the identical "**provi[sion]**" is included in the EN for Chapter 29, Gen. EN 29.36(d) (emphasis in original), as recognized by Roche, see Roche's Motion at 24-25. This issue arises from Defendant using an earlier version of the ENs than does Roche. See July 29, 2010 Oral Argument at 39:23- 40:52. The 2002 version used by Roche is "perfectly proper" because the subject entries were imported that year. Id. at 40:50-52.

> shelf life of the beta-carotene, and/or to increase or aid the beta-carotene's availability in the body.

Declaration of Robert Mitchell Russell, M.D., appended to Defendant's Opposition ("Russell Decl.") at 12-13.

Defendant has created a genuine issue whether the BetaTab 20% ingredients "render it particularly suitable for specific use," Gen. EN 29.36(d), namely "in making tablet or capsule forms of dietary or nutritional supplements," Russell Decl. at 11. This "specific use" contrasts with the "general use" of BetaTab 20% providing beta-carotene/provitamin A content and antioxidant activity. Gen. EN 29.36(d). Defendant's expert is highly qualified and has extensive experience researching carotenoids. See id. at 1-4. His opinion, based in part upon Roche's patent and marketing materials, see id. at 9, 11-13, concludes that "[t]he ingredients/formulation of the [BetaTab 20%] are very suitable for use in preparing the product for use in making tablet or capsule forms of dietary or nutritional supplements," id. at 11. Specifically, the sucrose "lends itself uniquely to permit the beta carotene preparation to be used in making tablets and/or for extrusion into capsules." Id. This expert testimony supports BetaTab 20%'s exclusion from Heading 2936 because the stabilizing ingredients make it suited for a specific purpose "rather than for general use." Gen. EN 29.36(d).

Roche during discovery conceded that certain "qualities render BetaTab 20% well suited for use in direct compression of tablets." Plaintiff's Response to Defendant's First Interrogatories and Request for Production Directed to Plaintiff, Response No. 71, at 29, attached to Defendant's Letter (July 29, 2010). According to Roche, as compared with another of its beta-carotene products, "BetaTab 20% has a higher concentration of beta carotene, is not dispersible in water below 20° C, and its particles have less extrusion loss in direct compression than other beta carotene particles or powders." Id. at 28. Roche's

explanation of these qualities creates a genuine issue as to whether the ingredients of BetaTab 20% "render it particularly suitable for specific use rather than for general use." Gen. EN 29.36(d).

Roche does not sufficiently resolve, for summary judgment purposes, this genuine issue concerning the function of the BetaTab 20% ingredients.[11] Roche's emphasis on the EN allowing for plasticized gelatin, see Plaintiff's Memorandum of Law in Reply to Defendant's Opposition to Plaintiff's Motion for Summary Judgment ("Roche's Reply") at 8, does not compel classification of BetaTab 20% under HTSUS Heading 2936 because Defendant's expert testified that the matrix which includes gelatin facilitates tableting and provides more than "stabilis[ation] for the purposes of preservation or transport," Gen. EN 29.36(d); see Russell Decl. at 12-13.[12]

Roche's efforts to counter Defendant's arguments demonstrate that summary judgment to classify BetaTab 20% under HTSUS Heading 2936 is inappropriate. Roche argues that the aid of absorption into the body is necessary "for beta-carotene to function

[11] Roche does establish that the stabilizing ingredients in BetaTab 20% are not in quantities greater than necessary to achieve stabilization and do not alter the molecule of beta-carotene. See Roche's Motion at 26-27 (citing Declaration of Joseph M. Spraragen ("Spraragen Decl.") Ex. 5: Deposition of Mitchell Russell, M.D., at 69:6-23, 64:12-65:3). Roche argues that "BetaTab 20% is suitable for general use as provitamin A." Id. at 27. However, Roche does not establish the absence of a genuine issue whether the stabilizing ingredients "render it particularly suitable for specific use rather than for general use." Gen. EN 29.36(d); see Roche's Motion at 23-30; Roche's Reply at 7-10.

[12] Roche relies on Customs having classified vitamins containing stabilizing gelatin under HTSUS Heading 2936. See Roche's Motion at 29 (citing Customs Headquarters Determination No. 953829 (July 26, 1993) ("HQ 953829"); Customs Headquarters Determination No. 955754 (August 22, 1994) ("HQ 955754"); Customs Headquarters Determination No. 955867 (August 22, 1994) ("HQ 955867"). These decisions do not warrant deference supporting Roche because each includes only scant analysis devoid of explanation as to why the stabilizing gelatin did not render those vitamins more suitable for their intended use as "animal feed." HQ 953829; HQ 955754; HQ 955867; see Skidmore, 323 U.S. at 140. Similarly, a Harmonized System Committee of the World Customs Organization decision relied upon by Roche does not address whether the stabilizers in Rovimix, an animal feed product containing beta-carotene, rendered the product more suitable for use as animal feed. See Roche's Motion at 28-29; Spraragen Decl. Ex. 2: Customs Co-operation Council, Classification of "Rovimix AD_3" (December 6, 1990). Roche also relies upon a Canadian International Trade Tribunal decision which it acknowledges is "not entitled to deference." Roche's Motion at 29-30.

as provitamin A," as opposed to a stabilizing ingredient characteristic that warrants exclusion from Heading 2936. Roche's Reply at 10. There is a genuine issue whether BetaTab 20% promotes absorption in common with all provitamin A products or in an enhanced manner to permit use as a tablet-form supplement. See Defendant's Opposition at 26. Although Roche and Defendant agree that BetaTab 20% must be "combined with tableting excipients . . . to be formed into a tablet," Roche's Facts ¶ 35; see Defendant's Factual Response ¶ 35, there is a genuine issue whether the stabilizing ingredients further render BetaTab 20% "particularly suitable for specific use rather than for general use." Gen. EN 29.36(d).

With respect to sucrose, Roche disputes Defendant's argument that this ingredient "'uniquely' permits BetaTab 20% to be used in making tablets and capsules." Roche's Reply at 8 (quoting Defendant's Opposition at 25). Defendant's expert based this conclusion on Roche's patent. See Russell Decl. at 12. Roche counters with supplemental expert opinion, based on Roche's patent, that "[t]he benefits of mechanical stability are not limited to dry products forms used in making tablets and capsules." Supplemental Declaration of John Claude Tritsch ¶ 5. This expert dispute evidences a genuine issue whether the sucrose renders BetaTab 20% "particularly suitable for specific use rather than for general use." Gen. EN 29.36(d). That sucrose and other BetaTab 20% ingredients are stabilizers does not compel classification under Heading 2936 given the genuine issue as to their additional functionality.

V
CONCLUSION

For the above stated reasons, Plaintiff Roche Vitamin, Inc.'s Motion for Summary

Judgment is DENIED.

__/s/ Evan J. Wallach____
Evan J. Wallach, Judge

Dated: December 23, 2010
New York, New York