

U.S. Court of Appeals for the Federal Circuit

ROCHE VITAMINS, INC., Plaintiff-Appellee, v. UNITED STATES,
Defendant-Appellant.

Appeal No. 2013–1568

Appeal from the United States Court of International Trade in No. 04-CV-0175,
Judge Richard K. Eaton.

Dated: November 20, 2014

ERIK D. SMITHWEISS, Grunfeld, Desiderio, Lebowitz, Silverman & Klestadt LLP, of New York, New York, argued for plaintiff-appellee. With him on the brief were ROBERT B. SILVERMAN and JOSEPH M. SPRARAGEN.

PATRICIA M. MCCARTHY, Assistant Director, Commercial Litigation Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for defendant-appellant. With her on the brief were STUART F. DELERY, Assistant Attorney General, and JEANNE E. DAVIDSON, Director. Of counsel on the brief were EDWARD N. MAURER and SHERYL A. FRENCH, Office of Assistant Chief Counsel, International Trade Litigation, United States Customs & Border Protection, of New York, New York. Of counsel was SAUL DAVIS, Attorney, Appellate Section, International Trade Litigation, International Trade Field Office, United States Department of Justice, of New York, New York.

Before PROST, *Chief Judge*, LOURIE and DYK, *Circuit Judges*.

LOURIE, *Circuit Judge*.

The United States (“the government”) appeals from the decision of the United States Court of International Trade reclassifying Roche Vitamin Inc.’s (“Roche”) product BetaTab 20% (“BetaTab”) as “Provitamins, unmixed” under subheading 2936.10.00 of the Harmonized Tariff Schedule of the United States (“HTSUS”). *See Roche Vitamins, Inc. v. United States*, 922 F. Supp. 2d 1353 (Ct. Int’l Trade 2013) (“*Opinion*”). Because the Court of International Trade correctly classified BetaTab under heading 2936, we affirm.

BACKGROUND

Roche imported BetaTab, which is a mixture containing beta-carotene, antioxidants, gelatin, sucrose, and cornstarch, and can be used as a source of Vitamin A in foods, beverages, and vitamin products. Beta-carotene crystalline makes up twenty percent of the mixture and is an organic colorant with provitamin A activity. Whether used as a colorant or provitamin A, beta-carotene must first be combined with other ingredients.

The United States Customs and Border Protection (“Customs”) classified BetaTab under HTSUS subheading 2106.90.97 as “[f]ood preparations not elsewhere specified or included.” *Id.* at 1356. Roche filed a protest to the liquidation of BetaTab, which Customs denied. *Id.* Roche then filed suit in the Court of International Trade and moved for summary judgment.

Roche argued that BetaTab was classifiable either as a “coloring matter” under HTSUS subheading 3204.19.35, and eligible for duty-free entry pursuant to the Pharmaceutical Appendix, or, alternatively, as a provitamin under HTSUS heading 2936. The Court of International Trade denied Roche’s motion for summary judgment. *Roche Vitamins, Inc. v. United States*, 750 F. Supp. 2d 1367, 1382 (Ct. Int’l Trade 2010). The court concluded that genuine issues of material fact as to the principal use of BetaTab and the functionality of BetaTab’s ingredients other than beta-carotene precluded summary judgment. *Id.*

Following trial, the Court of International Trade first determined that the principal use of BetaTab was as a source of provitamin A in foods or vitamin products, rather than as a coloring matter. *Opinion* at 1360. As part of the principal use analysis, the court found that “BetaTab was developed for use in vitamin products and its actual use during the relevant time period was predominantly as a source of Provitamin A for vitamin products.” *Id.* The court explained that the “high concentration and high bioavailability of beta-carotene in the merchandise [made] it preferable for use in dietary supplement tablets.” *Id.* at 1361. The court also noted that BetaTab was developed specifically “for use in high potency and anti-oxidative vitamin tablets.” *Id.*

The court then considered whether BetaTab was properly classified under HTSUS heading 2936 as a provitamin. Citing Note 1 to Chapter 29 and the Explanatory Notes to Chapter 29, the court explained that a product would not properly be classified under heading 2936 “if the quantity of a stabilizing agent added to an item of [heading 2936] is more than is necessary for transport or preservation, or the nature of the stabilizing agent alters the character of the basic product so as to render it ‘particularly suitable for specific use.’” *Id.* at 1358–59. The court noted that “[a]dded ingredients that make a chemical highly capable of a use that is *not an ordinary use of* chemicals of the heading . . . will render the item ‘particularly suitable for specific use rather than for general use’ and exclude it from classification in the headings of Chapter 29.” *Id.* at 1359 (emphasis in original).

Based on the evidence presented at trial, the court found that a stabilizing matrix of some kind is necessary for any beta-carotene

product, and beta-carotene must be processed and combined with other ingredients to be commercially usable as either a provitamin A or colorant. *Id.* at 1362. The court found that Roche's manufacturing process did not change BetaTab's functionality as a provitamin or change the character of beta-carotene as a source of provitamin A. *Id.* According to the court, there was "no evidence that the merchandise's non-beta-carotene ingredients enhance absorption or bioavailability of the beta-carotene in a manner greater than any other stabilizing matrix." *Id.* The court found that although BetaTab was highly suitable for tableting, BetaTab itself contained no ingredients "specifically prepared for tableting." *Id.* The court noted that the stabilizers used in BetaTab were essentially the same as those used to stabilize other vitamins and other beta-carotene products that are marketed for use as colorants. *Id.*

The court concluded that "[i]t was demonstrated as a matter of fact at trial that BetaTab's additional non-beta-carotene ingredients, added as stabilizers, do not make[BetaTab] particularly suitable for a specific use." *Id.* at 1363. As a result, the court concluded that the addition of the stabilizing ingredients was permissible under Note 1 to Chapter 29, and did not exclude the merchandise from classification under heading 2936. *Id.* at 1364. The court concluded that, because BetaTab was "elsewhere included," Customs' classification under heading 2106 was incorrect and BetaTab was properly classified under 2936. *Id.* The court then reasoned that because BetaTab is a provitamin compound, BetaTab was properly classified further under subheading 2936.10.00. *Id.* at 1365.

The government timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(5).

DISCUSSION

We review questions of law *de novo*, including the interpretation of HTSUS terms. *Home Depot U.S.A., Inc. v. United States*, 491 F.3d 1334, 1335 (Fed. Cir. 2007). The determination of whether a particular product fits within that interpretation is a question of fact, reviewable for clear error. *Nat'l Advanced Sys. v. United States*, 26 F.3d 1107, 1109 (Fed. Cir. 1994).

Merchandise imported into the United States is classified under the HTSUS. The HTSUS scheme is organized by headings, each of which has one or more subheadings; the headings set forth general categories of merchandise, and the subheadings provide a more particularized segregation of the goods within each category. The classification of merchandise under the HTSUS is governed by the principles set forth in the General Rules of Interpretation ("GRIs") and the Addi-

tional U.S. Rules of Interpretation. See *Orlando Food Corp. v. United States*, 140 F.3d 1437, 1439 (Fed. Cir. 1998). GRI 1 provides that “for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the [remaining GRIs.]” GRI 1. The Chapter Notes are an integral part of the HTSUS, and have the same legal force as the text of the headings. *Degussa Corp. v. United States*, 508 F.3d 1044, 1047 (Fed. Cir. 2007).

The relevant section of the HTSUS reads as follows:

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

Heading 2936, HTSUS (2002).

HTSUS Note 1 to Chapter 29 provides: “Except where the context otherwise requires, the headings of this Chapter apply only to: . . . (f) The products mentioned in (a),(b), (c), (d) or (e) above with *an added stabilizer* (including an anticaking agent) *necessary for their preservation or transport.*” HTSUS Ch. 29, n.1 (2002) (emphases added).

The Explanatory Notes for HTSUS Chapter 29 provide further insight as to the proper classification of merchandise under heading 2936. Explanatory Notes are not legally binding, but may be consulted for guidance and are generally indicative of the proper interpretation of a tariff provision. *Motorola, Inc. v. United States*, 436 F.3d 1357, 1361 (Fed. Cir. 2006). Explanatory Note 29.36 states:

This heading includes: . . .

- (a) Provitamins and vitamins, whether natural or reproduced by synthesis, and derivatives thereof used primarily as vitamins. . . .
- (d) The above products diluted in any solvent (e.g., ethyl oleate, propane-1,2-diol, ethanediol, vegetable oils).

The products of this heading may be stabilised for the purposes of preservation or transport:

- by adding anti-oxidants,
- by adding anti-caking agents (e.g. carbohydrates),
- by coating with appropriate substances (e.g. gelatin, waxes or fats), whether or not plasticized, or

- by adsorbing on appropriate substances (e.g., silicic acid),
provided that the quantity added or the processing in no case exceeds that necessary for their preservation or transport and that the addition or processing *does not alter the character of the basic product and render it particularly suitable for specific use rather than for general use.*

Explanatory Notes to the Harmonized Commodity Description and Coding System 29.36 (3d ed. 2002) (emphasis added) (“Explanatory Notes”); J.A. 336.

The government argues that heading 2936 excludes products that have undergone processing that renders them suitable for a specific use, and BetaTab is processed to such a degree that it has been rendered particularly suitable for use as a nutritional ingredient in vitamin tablets and capsules. The government contends that nothing in either the text or the Explanatory Notes to Chapter 29 supports the Court of International Trade’s new interpretation that a “specific use” disqualifying classification under Chapter 29 must necessarily be “a use that is not an ordinary use of chemicals of the heading.” *E.g.*, Appellant’s Br. 10.

Roche responds that BetaTab is properly classified as a provitamin under heading 2936 and it satisfies the limitations of Note 1 to Chapter 29 and Explanatory Note 29.36. Roche argues that BetaTab contains no ingredients that specifically prepare it for use in tablets, and the evidence at trial demonstrated that BetaTab is suitable for general use, *i.e.*, for use in tablets, capsules, foods, and even as a colorant. Roche contends that the added stabilizing agents do not render BetaTab particularly suitable for a specific use rather than for general use, and BetaTab must first be combined with tableting excipients to be formed into a tablet.

We agree with Roche that BetaTab is properly classified as a provitamin under heading 2936 because it fulfills the description in the statutory heading and satisfies the limitations of both Note 1 to Chapter 29 and Explanatory Note 29.36. It is a stipulated fact that beta-carotene has provitamin A activity, J.A. 84, and there is no dispute regarding the Court of International Trade’s finding that BetaTab is accurately described as a provitamin of heading 2936, subject to the limitations of Note 1 to Chapter 29 and Explanatory Note 29.36. Thus, because in this case no interpretation of HTSUS terms is before us, we review the conclusions of the Court of International Trade for clear error.

Note 1(f) to Chapter 29 permits the addition of stabilizer ingredients to BetaTab, as long as the amount of stabilizer added is not more

than necessary for preservation or transport. In its denial of summary judgment, the Court of International Trade held that “the stabilizing ingredients . . . are not in quantities greater than necessary to achieve stabilization.” *Roche*, 750 F. Supp. 2d at 1381 n.11. The parties did not dispute this point at trial, *Opinion* at 1359 n.5, and the government acknowledged during oral argument that it is not raising the argument now on appeal, Oral Argument at 7:41, *Roche Vitamins, Inc. v. United States*, No. 2013–1568, available at <http://www.cafc.uscourts.gov/oral-argument-recordings/all/roche-vitamins.html>. Thus, we do not need to address this point.

Explanatory Note 29.36 expands on Note 1(f) to Chapter 29 and permits the addition of stabilizer ingredients if the addition or processing does not (1) alter the character of the basic product and (2) render it particularly suitable for specific use rather than for general use. The government’s expert testified, and the Court of International Trade found, that Roche’s manufacturing process does not change BetaTab’s functionality as provitamin A or change the character of the beta-carotene as provitamin A. J.A. 307; *Opinion* at 1362. The government does not provide any evidence to the contrary. We therefore conclude that the Court of International Trade did not clearly err in finding that the additional ingredients and processing do not alter the character of the beta-carotene.

Nor does the addition of stabilizer ingredients render the basic product, beta-carotene, particularly suitable for specific use rather than for general use. Expert testimony established that the sucrose and gelatin additives function as stabilizers and do not “specifically prepare [BetaTab] for tableting.” J.A. 165. In addition, the record demonstrates that BetaTab has no ingredients added specifically for tableting, such as tableting excipients. J.A. 164, 165. The stabilizers used in BetaTab were essentially the same as those used to stabilize other vitamins and other beta-carotene products that were marketed for use as colorants. J.A. 134, 137, 144, 213; *Opinion* at 1362. Although the high concentration and high bioavailability of beta-carotene in BetaTab make it preferable for use for the manufacture of tablets, no evidence supports the assertion that the added stabilizers make BetaTab particularly suitable for tableting. As a result, the Court of International Trade did not clearly err in finding that the addition of stabilizer ingredients did not render BetaTab particularly suitable for the specific use of tableting.

Notably, BetaTab also remains suitable for general use. Expert testimony established that BetaTab is “well-suited for fortifying foods with provitamin A,” J.A. 235, and “is suitable for general use as provitamin A,” J.A. 307. BetaTab can thus be used as a source of

vitamin A in foods, beverages, and vitamin products. Consequently, the Court of International Trade did not clearly err in finding that BetaTab remains suitable for general use.

The government places significant emphasis on the Court of International Trade's conclusion that "[a]dded ingredients that make a chemical highly capable of a use that is *not an ordinary use* of chemicals of the heading . . . will render the item 'particularly suitable for specific use rather than for general use.'" *E.g.*, Appellant's Br. 10. Although the court appears to have erred in this overly-narrow interpretation of Explanatory Note 29.36, the record demonstrates that the addition of stabilizer ingredients did not render BetaTab particularly suitable for specific use rather than for general use. Thus, the court did not clearly err in classifying BetaTab as a provitamin under heading 2936.

Customs classified BetaTab under heading 2106, which covers "[f]ood preparations *not elsewhere specified*." *Opinion* at 1356 (emphasis added). Because BetaTab is properly classified under 2936, Customs' classification under heading 2106 cannot stand because BetaTab is elsewhere specified. Assuming that BetaTab is properly classified under heading 2936, the government does not dispute that BetaTab is properly further classified as "Provitamins, unmixed" under subheading 2936.10.00.

CONCLUSION

Because the addition of stabilizer ingredients does not render BetaTab particularly suitable for specific use rather than for general use, we conclude that the Court of International Trade did not err in classifying BetaTab as "Provitamins, unmixed" under subheading 2936.10.00. Accordingly, the judgment of the Court of International Trade is affirmed.

AFFIRMED