SLIP OP. 05–47

BEFORE: RICHARD K. EATON, JUDGE

RESER'S FINE FOODS, INC., D/B/A SIDARI'S ITALIAN FOODS, PLAINTIFF, v. UNITED STATES, DEFENDANT.

COURT NO. 00–00021

[Plaintiff's motion for summary judgment denied; Defendant's cross-motion for summary judgment granted]

Dated: April 12, 2005

*Fitch, King and Caffentzis* (*James Caffentzis*), for plaintiff Reser's Fine Foods, Inc., d/b/a Sidari's Italian Foods.

*Peter D. Keisler*, Assistant Attorney General, Civil Division, United States Department of Justice; *Barbara S. Williams*, Acting Attorney in Charge, International Trade Field Office (*Mikki Graves Walser*); *Michael W. Heydrich*, of counsel, Office of the Assistant Chief Counsel for United States Customs and Border Protection, for defendant United States.

MEMORANDUM

EATON, *Judge*: This case is again before the court on cross-motions for summary judgment pursuant to USCIT R. 56. Previously, both parties made similar motions, each of which was denied because there remained questions with respect to material facts. *See Reser's Fine Foods, Inc. v. United States*, 27 CIT ___ , slip op. 03–117 (Sept. 5, 2003) ("*Reser's I*"). Now, following renewed discovery and the filing of new affidavits, interrogatory responses, deposition transcripts, and physical and documentary evidence, each party has renewed its motion. Plaintiff Reser's Fine Foods, Inc., d/b/a Sidari's Italian Foods ("Reser's") again challenges the United States Customs Service's ("Customs")[1] classification of its entries of artichokes as "Other veg-

[1] Effective March 1, 2003, the Unites States Customs Service was renamed the Bureau of Customs and Border Protection. *See* Reorganization Plan Modification for the Dep't of Homeland Security, H.R. Doc. 108–32 at 4 (2003).

etables prepared or preserved otherwise than by vinegar or acetic acid, not frozen, other than products of heading 2006 . . . Other vegetables and mixtures of vegetables . . . Artichokes," under subheading 2005.90.80 of the Harmonized Tariff Schedule of the United States (1998) ("HTSUS") and subject to a tariff rate of 15.8% *ad valorem*. Plaintiff argues that the merchandise is properly classifiable under HTSUS subheading 0711.90.60 as "Vegetables provisionally preserved (for example, by sulfur dioxide gas, in brine, in sulfur water or in other preservative solutions), but unsuitable in that state for immediate consumption . . . Other vegetables; mixtures of vegetables . . . Other vegetables; mixtures of vegetables," subject to a tariff rate of 9.1% *ad valorem*. By its cross-motion, defendant United States, on behalf of Customs, again maintains that the merchandise is properly classifiable under HTSUS subheading 2005.90.80, and asks the court to deny plaintiff's motion and dismiss this action. The court has jurisdiction pursuant to 28 U.S.C. § 1581(a) (2000).

This court may resolve a classification issue by means of summary judgment. Summary judgment is appropriate "if the pleadings, depositions, answer to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact. . . . " USCIT R. 56(c). Summary judgment of a classification issue "is appropriate when there is no genuine dispute as to the underlying factual issue of exactly what the merchandise is." *Bausch & Lomb*, 148 F.3d at 1365 (citing *Nissho Iwai Am. Corp. v. United States*, 143 F.3d 1470, 1472 (Fed. Cir. 1998); *IKO Indus., Ltd. v. United States*, 105 F.3d 624, 626–27 (Fed. Cir. 1997); *Rollerblade, Inc. v. United States*, 112 F.3d 481, 483 (Fed. Cir. 1997). Under 28 U.S.C. § 2639(a)(1), Custom's classification of merchandise is presumed to be correct. In the context of summary judgment, however, since there are no disputes with respect to the material facts, the presumption does not shift the burden to the plaintiff. *See Mead Corp. v. United States*, 283 F.3d 1342, 1346 (Fed. Cir. 2002) (where court determines that there is no dispute of material facts, its "review of the classification of goods collapses into a determination of the proper meaning and scope of HTSUS terms, which, as a matter of statutory construction, is a question of law."). For the reasons set forth below, the court denies plaintiff's summary judgment motion, and grants that of defendant United States.

## BACKGROUND

In the context of their first cross-motions for summary judgment, the parties agreed that (1) "The merchandise . . . was imported from Spain [and] consists of 88–1/5 ounces of quartered artichoke hearts in a solution of water and acetic acid (0.1%), salt (1.2%) and citric acid (0.6%) packaged in No. 10 cans. The pH of the liquid solution in the imported cans is 3.97"; (2) "Citric acid is used to enhance flavors, increase preservative effectiveness, retard discoloration and con-

serve energy by reducing heat-processing requirements in vegetable processing"; and (3) "In Spain, the merchandise . . . is packed in cans which are [then] subjected to a thermal process which expels air, then hermetically sealed and further heated for the purpose of rendering the product commercially sterile." Parties' Joint Statement of Material Facts as to Which There Are No Genuine Issues to be Tried ¶¶ 6–8 ("Parties' Joint Statement"). The evidence submitted in connection with the instant motions, as well as the parties' stated agreement with respect to certain other material facts, will be discussed in the context of the issues presented.

## DISCUSSION

Classification of merchandise under the HTSUS is governed by the General Rules of Interpretation ("GRI"). *See Carl Zeiss, Inc. v. United States*, 195 F.3d 1375, 1379 (Fed. Cir. 1999) (citing *Baxter Healthcare Corp. of P.R. v. United States*, 182 F.3d 1333, 1337 (Fed. Cir. 1999)) (noting that the HTSUS General Rules of Interpretation (GRI) and the Additional U.S. Rules of Interpretation (U.S. GRI) govern the proper classification of all merchandise and are applied in numerical order). GRI 1 states that "for legal purposes, classification shall be determined according to the terms of the headings and any relative section or chapter notes. . . . " GRI 1. GRI 6 states that "the classification of goods in the subheadings of a heading shall be determined according to the terms of those subheadings and any related subheading notes and, *mutatis mutandis* to the [General Rules of Interpretation] on the understanding that only subheadings at the same level are comparable." GRI 6. Furthermore, "[w]hen . . . a tariff term is not defined in either the HTSUS or its legislative history, 'the term's correct meaning is its common meaning.' " *Rocknel Fastener, Inc. v. United States*, 267 F.3d 1354, 1356 (Fed. Cir. 2001) (quoting *Mita Copystar Am. v. United States*, 21 F.3d 1079, 1082 (Fed. Cir. 1994)); *see also Smith v. United States*, 508 U.S. 223, 228 (1993) ("When a word is not defined by statute, we normally construe it in accord with its ordinary or natural meaning."). In ascertaining the meaning of undefined terms, "the court may rely upon its own understanding, dictionaries and other reliable sources." *Medline Indus., Inc. v. United States*, 62 F.3d 1407, 1409 (Fed. Cir. 1995); *see also Brookside Veneers, Ltd. v. United States*, 847 F.2d 786, 789 (Fed. Cir. 1988) ("To assist it in ascertaining the common meaning of a tariff term, the court may . . . consult lexicographic and scientific authorities, dictionaries, and other reliable information sources."). Finally, as an aid to understanding the meaning of a tariff term, "a court may refer to the Explanatory Notes . . . which do not constitute controlling legislative history but nonetheless are intended to clarify the scope of HTSUS subheadings and to offer guidance in interpreting subheadings." *Mita*, 21 F.3d at 1082 (citing *Lynteq, Inc. v. United*

*States*, 976 F.2d 693, 699 (Fed. Cir. 1992)); see Harmonized Commodity Description and Coding System (3d ed. 2002) ("Explanatory Notes").

In order for merchandise to be classified under HTSUS heading 07.11, it must be "unsuitable for immediate consumption as imported."[2] In denying the parties' first cross-motions for summary judgment, the court found that there were material questions of fact with respect to the suitability of the subject merchandise for immediate consumption. *See Resers I*, 28 CIT at ___ , slip op. 03–117 at 3. While both parties now agree that the artichokes are edible in their imported condition, *see* Pl.'s Br. in Supp. Supplemental Mot. S.J. at 7 ("Pl.'s Br."); Def.'s Mem. in Opp'n to Pl.'s Mot. S.J. and in Supp. Def.'s Cross-Mot. S.J. at 8 ("Def.'s Mem."), plaintiff continues to contend that because the artichokes have "a disagreeable taste which prevents them from being put to their intended use without further processing, " they are unsuitable for immediate consumption. Pl.'s Ex. 7, Goellnitz Aff. ¶ 9. The "further processing" plaintiff refers to consists entirely of removing the artichokes from their shipping solution and spraying them with water. *Id.* at ¶ 8. "In this case, plaintiff has shown that the excess preservative solution must be removed by processing the artichokes after importation. This intermediate processing is a necessary step in making the artichokes suitable for their intended use as an ingredient in artichoke salads." Pl.'s Br. in Supp. Mot. S.J. at 7–8. "The artichokes are dumped on the conveyor. They go through a rinse." Pl.'s Ex. 2, Goellnitz Dep., at 22. The rinse consists of "eleven jets that shoot water in a fan shape formation onto the product. . . . " *Id.* at 24. Mr. Goellnitz estimated that, given the speed of the conveyor belt, the spraying process takes "probably 20, 30 seconds." *Id.* at 25. After rinsing, the conveyor belt takes the artichokes to a sink where they are mixed with peppers, lemon juice, corn oil, spices, and preservatives. *Id.* at 22. The mixture is then put in jars and sold as marinated artichoke salad. *Id.* at 28.

Thus, for plaintiff, the important factor is that, even though the artichokes might be edible as imported, because of their disagreeable taste, they cannot be put to the use for which they were imported without being rinsed. In other words, plaintiff insists that "the term 'unsuitable for immediate consumption' must refer to those edible vegetables which are not in condition for their intended use absent further treatment or processing." Pl.'s Br. at 7.

Defendant does not dispute that the artichokes as imported have a

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[2] In *Reser's I*, the court dismissed each party's motion for summary judgment because questions remained as to material facts relating to the phrases "provisionally preserved" and "unsuitable for immediate consumption" found in HTSUS heading 07.11. As the court finds that the phrase "unsuitable for immediate consumption" excludes the artichokes from being classified under HTSUS 07.11, matters relating to "provisionally preserved" are not discussed.

disagreeable taste. Def.'s Mem. at 9.[3] Rather, defendant relies on the notion that the artichokes, as imported, are edible, and are suitable for consumption in the same manner as artichokes sold at retail to the general public.[4] Relying on the evidence of various experts,[5] defendant explains:

> Just as their canned counterparts which are put up for retail sale and suitable for immediate consumption, the imported arctichoke hearts are suitable for immediate consumption upon entry into the United States. The imported merchandise contains the same ingredients as canned artichoke hearts which are put up for retail sale. . . . The amount of acid, as reflected by the pH of the solution, is consistent with that found in similar imported canned artichoke hearts available in retail stores. The imported artichokes hearts have similar or lower levels of salt and preservatives than other canned artichoke hearts which are suitable for immediate consumption.
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> Finally, the imported artichokes are, or can be, used in the same manner as other canned artichoke hearts which are available in retail stores. . . . Simply put, the imported canned artichoke hearts are suitable for immediate consumption in the same manner as goods of its class which are put up for retail sale.

Def.'s Mem. at 8–9 (internal citations omitted).

For its part, plaintiff does not claim that defendant is wrong in its contention that the artichokes, as imported, are the same as those sold at retail. Rather, it contends that all artichokes imported in the subject merchandise's condition must be rinsed off. *See* Pl.'s Br. at 7 ("If not used as an ingredient in marinated salads (plaintiff's use), such artichokes are used as ingredients in cooking or as pizza toppings. To the best of plaintiff's knowledge, the undesirable or disagreeable taste does not change and the preservative solution must be removed before being put to use."); *see also* Pl.'s Br. in Resp. to Ct.

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[3] Although not explicitly conceding that the artichokes have a "bitter and salty" taste, defendant at no point disputes this fact and indeed implicitly concedes it in its argument. *See* Def's Mem. at 9; see also Def.'s Resp. to Ct. Order Dated Feb. 23, 2005, at 2 ("[T]he Government cannot dispute that the imported merchandise has a 'disagreeable' taste prior to draining and rinsing. . . . ").

[4] There is no disagreement that the artichokes are, in fact, suitable for consumption in the same manner as artichokes sold at retail to the general public. *See* Pl.'s Br. in Resp. to Ct. Order of Feb. 23, 2005, at 1–2, and Def.'s Resp. to Ct. Order Dated Feb. 23, 2005, at 3.

[5] Defendant relies on the declaration of Robert F. Epperson, a technical consultant for the vegetable processing industry specializing in quality control and food safety issues relating to artichokes, and the declaration and discovery responses of Dr. Sher Paul Singh, a professor with the Michigan State University School of Packaging and a consultant to the packaging industry.

Order of Feb. 23, 2005, at 1 ("[T]he artichokes sold at 'retail' require the same draining of the brine solution and washing or rinsing with water prior to use.").

The court agrees that defendant has demonstrated that the artichokes are suitable for immediate consumption,[6] as imported. What plaintiff refers to as "further processing" is no more than removing the artichokes from the solution in which they were shipped, then spraying them with water. It is undisputed that a retail consumer would be obliged to perform the same tasks. It can hardly be said that similar merchandise bought at retail is unfit to be consumed immediately. To accept plaintiff's interpretation, the court would have to assume that washing the grit from lettuce before using it in a salad would mean that the lettuce, as it came from the grocery store, was not suitable for immediate consumption.

Indeed, to agree with plaintiff would require the court to alter the ordinary meaning of the phrase "unsuitable for immediate consumption." As previously noted, where a tariff term is not defined, it is presumed to have its common meaning. *See Rocknel Fastener*, 267 F.3d at 1356. In order to determine the common meaning of the phrase "unsuitable for immediate consumption," the court must first determine the meaning of the word "suitable." In this context, the word "suitable" means "adapted to a use or purpose: FIT <food [suitable] for consumption> ." Webster's Third New International Dictionary 2286 (3d ed. 1993). Here, there is no question that the artichokes are "fit" for immediate consumption, as they are edible. *See A. Giurlani & Bros., Inc. v. United States*, 9 CIT 60 (1985) (not reported in the Federal Supplement) (denying cross-motions for summary judgment where question as to whether or not merchandise was edible was found to raise an issue of material fact). That the artichokes might not be pleasant to eat prior to rinsing does not render them unfit for immediate consumption as that phrase is commonly understood.

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[6] Even if plaintiff were to prevail on the question as to the artichokes' suitability for immediate consumption, the merchandise could not be classified under HTSUS subheading 0711.90.60. The Explanatory Note accompanying that subheading states:

> This heading applies to vegetables which have been treated *solely* to ensure their provisional preservation during transport or storage prior to use (e.g., by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), **provided** they remain unsuitable for immediate consumption in that state.

Explanatory Note 07.11 (emphasis added; emphasis in original).

As stated in the Parties' Joint Statement, "[t]he merchandise . . . was imported from Spain [and] consists of 88–1/5 ounces of quartered artichoke hearts in a solution of . . . citric acid (0.6%). . . . " and "[c]itric acid is used to *enhance flavors*, increase preservative effectiveness, retard discoloration and conserve energy by reducing heat-processing requirements in vegetable processing." Parties' Joint Statement ¶¶ 6–7 (emphasis added).

CONCLUSION

The court finds that because the subject merchandise is suitable for immediate consumption, it is excluded from classification under HTSUS heading 07.11 and is properly classified under subheading 2005.90.80 of the HTSUS. Therefore, the court denies plaintiff's motion for summary judgment and grants that of defendant United States. Judgment shall be entered accordingly.

**SLIP OP. 05–48**

INABATA SPECIALTY CHEMICALS, Plaintiff, v. UNITED STATES, Defendant.

Court No. 01–00600

[Judgment for plaintiff as to tariff classification.]

Dated: April 13th, 2005

*Grunfeld, Desiderio, Lebowitz, Silverman Klestadt LLP*, (*Erik D. Smithweiss, Joseph M. Spraragen, Robert B. Silverman*, and *William F. Marshall*) for plaintiff.

*Peter D. Keisler*, Assistant Attorney General, *David M. Cohen*, Director, *Jeanne E. Davidson*, Deputy Director, *Barbara S. Williams*, Attorney in Charge, Commercial Litigation Branch, Civil Division, United States Department of Justice (*Bruce N. Stratvert*), *Chi S. Choy*, Attorney, Office of the Assistant Chief Counsel, International Trade Litigation, United States Customs and Border Protection, of counsel, for defendant.

**OPINION**

**RESTANI, Chief Judge:**

This matter is before the court following trial. The merchandise to be classified for tariff purposes is one entry, No. FYI–2004818–3, of chondroitin sulfate ("CS"), entered for consumption on January 22, 2001, and liquidated on April 6, 2001. *See* Customs Protest Form (May 18, 2001).

The merchandise at issue entered in bulk powder form and was packaged for retail sale as a dietary supplement according to U.S. Food and Drug Administration ("FDA") requirements. The United States Bureau of Customs and Border Protection of the Department of Homeland Security ("Customs")[1] classified the CS at issue under Harmonized Tariff Schedule of the United States ("HTSUS") subheading 3913.90.20, providing for "Natural polymers . . . and modi-

[1] The United States Customs Service was renamed the Bureau of Customs and Border Protection of the Department of Homeland Security, effective March 1, 2003. *See* H.R. Doc. No. 108–32 (2003).

fied natural polymers . . . not elsewhere specified or included, in primary forms: Other: . . . Polysaccharides and their derivatives," dutiable at the rate of 5.8% *ad valorem*.

Plaintiff claims the merchandise is classifiable under a duty-free provision, HTSUS subheading 3001.90.00, as "other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included . . . Other." In the alternative, plaintiff claims that the merchandise should be classified under HTSUS subheading 0410.00.00, as "Edible products of animal origin, not elsewhere specified or included," and dutiable at the rate of 1.1%. All duties have been paid; the classification was timely protested and protest was denied. The court has jurisdiction pursuant to 28 U.S.C. § 1581(a) (2000).

## *UNDISPUTED FACTS*

It is undisputed that the merchandise at issue is prepared from bovine cartilage and is an animal substance or product, *see* Pretrial Order at Sch. C, ¶ 19, thus satisfying the first requirement of plaintiff's claimed classification. It is also undisputed that it is a natural polysaccharide polymer as provided in the classification chosen by Customs. *Id*. Because, however, plaintiff's primary claimed classification is a use provision, it will prevail over Customs' classification, if plaintiff's classification applies. *See Totes, Inc. v. United States*, 69 F.3d 495, 499 n.3 (Fed. Cir. 1995) (quoting *E.M. Chems. v. United States*, 920 F.2d 910, 915–16 (Fed. Cir. 1990)) (noting that courts have held that "when two or more tariff categories are equally descriptive of an item, one that describes a use governs over one which describes the composition of the item"). Accordingly, the focus of the dispute is whether CS is prepared for a therapeutic or prophylactic use.

CS is widely reported to be effective in treating osteoarthritis ("OA"). Pretrial Order at Sch. C, ¶ 10. Pursuant to FDA regulations, CS is not marketed as a treatment or cure for OA or any other disease. Trial Transcript ("TR") at 147. The parties agree CS is not a food, foodstuff, beverage, or food supplement.[2] CS is required by the FDA, however, to be marketed as a dietary supplement, and it is. *Id*.

## *FINDINGS OF FACT*

_____ CS is imported in a bulk powder form much like aspirin. *Id*. at 119–20, 201–02. The CS at issue is manufactured to a purity of 90%,[3] which was standard in the industry at the time of importation, and determined by commercially-used testing procedures. *Id*. at 207,

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[2] Chapter 30, in which the plaintiff's claimed classification is found, excludes foods and beverages. *See* HTSUS chapter 30, note 1(a).

[3] In some countries a purity of 98% is considered pharmaceutical grade. *Id*. at 208. As

211. Defendant's witness, Anna Plaas, Ph.D. (Biochemistry), testified as to a type of testing that could detect substances not tested for commercially, but such testing was not available at the time of import and does not appear to be used commercially. *Id.* at 279–80. The manner of manufacture is similar throughout the CS industry. *Id.* at 202–03. The merchandise is sold at retail in the form of pills, tablets, or capsules—as over-the-counter drugs are. *Id.* at 120, 141, 159–61.

As the court ruled from the bench at the conclusion of the trial, the evidence was overwhelming and essentially uncontroverted that CS is prepared for, bought and sold and imported for therapeutic use. *Id.* at 414–16. Thus, on the face, plaintiff would seem to prevail. As defendant readily admits, plaintiff produced numerous documents from various sources, which demonstrate that in the commercial world, tablets, capsules, pills, etc., containing CS, often in combination with glucosamine, are understood to be specifically intended for OA relief. Def.'s Post-Trial Br. at 8–9; *see e.g.*, Pl.'s Ex. 22–65 (various published accounts of CS's affect on OA). Defendant concedes that pain relief is therapeutic. Tr. at 414. None of its witnesses disagreed with this conclusion. Otherwise, drugs such as aspirin would not be considered therapeutic, which they clearly are.

One of the defendant's experts, Richard Lee Nahin, Ph.D. (Neuroscience), who was called to explain an ongoing clinical trial of CS, opined that CS was an alternative medicine that is used and prepared for a therapeutic purpose, i.e., OA relief. *Id.* at 360. Another defense expert stated that pain relief and relief of symptoms are therapeutic uses. *Id.* at 317, 319. And the third of defendant's experts agreed that the easing of pain is a therapeutic action. *Id.* at 393. Thus, in the ordinary common meaning of the term, as testified to by defendant's experts, not just plaintiff's, CS is prepared for a therapeutic use.[4]

Plaintiff's medical experts also confirmed that CS is prescribed by physicians or self-prescribed for OA pain relief. *Id.* at 40 (Roland W. Moskowitz, M.D.); 94–95, 129 (Jason Theodosakis, M.D.). Defendant's witnesses did not disagree. *See*, *e.g.*, *id.* at 392. There was no evidence that CS is used as a food supplement, such as a vitamin, for general health reasons.

What the court cannot decide is whether CS actually does what it is prepared, marketed, and bought for, that is, provide pain relief for OA sufferers. Dr. Moskowitz, who has an extensive background in OA research, teaching, and treatment, testified about various studies which show some effect, particularly two meta-analyses (analy-

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indicated, the CS at issue is not subject to FDA regulation in the United States as a drug. *Id.* at 147.

[4] The parties did not focus on prophylactic or disease prevention use, and the court does not find that CS is prepared for such a use. One might consider the presence of the word "prophylactic" as indicative of the breadth of the claimed classification.

ses of a number of studies) which show some efficacy for CS products in the treatment of OA. *See e.g., id.* at 27–37 (discussing Pl.'s Ex. 18, 19). There was also considerable discussion of a larger National Institutes of Health study to test the efficacy of CS. *Id.* at 43–50. At the time of trial, the study was incomplete.

Defendant's medical expert, Frederic C. McDuffie, M.D., however, criticized the completed studies and opined that there was no solid evidence of the efficacy of CS as an OA treatment. *Id.* at 306–12. Defendant's biochemistry expert, Robert E. Olson, M.D., Ph.D., also opined that the various studies did not prove CS was a useful treatment for OA pain. *Id.* at 369.[5] Further, the court views Dr. Theodosakis's testimony on this point with caution, as he has a personal interest in seeing CS generally recognized as a treatment for OA. His practice and reputation center on that premise.[6] His belief may be sincere but it is not unbiased. Thus, the court credits Dr. Theodosakis's testimony on marketing, manner of sale, and use as a therapeutic product because it was consistent with the uncontradicted testimony of Larry J. Kolb and Alfred Baumeler, plaintiff's marketing witnesses. The court does not give weight, however, to his testimony on efficacy, although it largely credits the testimony on this point by Dr. Moskowitz, as well as that of defendant's witnesses, Dr. McDuffie and Dr. Olson. Nonetheless, whether Dr. Moskowitz or, on the other hand, defendant's experts are correct as to the degree of proof of the efficacy of CS, there is a body of scientific evidence to support the marketing and public perception of CS as an OA treatment. What remains is simply a point of scientific and medical debate which is, as yet, unresolved, i.e., whether CS works.

## *CONCLUSIONS OF LAW*

_____ While determining into what classification provision merchandise falls is a question of fact, the meaning of tariff provisions is a question of law. *Universal Elecs. Inc. v. United States*, 112 F.3d 488, 491 (Fed. Cir. 1997). According to HTSUS General Rule of Interpretation No. 1, "classification shall be determined according to the terms of the headings and any relative section or chapter notes." As indicated previously and as conceded by the parties, HTSUS Heading 3001 is a "use" provision. HTSUS Additional U.S. Rule of Interpretation 1(a) provides that "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 im-

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[5] Some of Dr. Olson's analysis of the meta-analyses was effectively contradicted in rebuttal, but the court accepts his overall conclusion that efficacy has not been shown to a high level of certainty.

[6] Dr. Theodosakis is a member of the steering oversight committee for the National Institutes of Health trial; and the use of CS in treating OA is "one of the hallmarks" of his communications with patients and medical professionals. *Id.* at 90–92.

portation, of goods of that class or kind to which the imported goods belong, and the controlling use is the principal use."

Common meaning of terms in a tariff statute controls. *Medline Indus., Inc. v. United States*, 62 F.3d 1407, 1409 (Fed. Cir. 1995); *Trans-Atlantic Co. v. United States*, 471 F.2d 1397, 1398 (C.C.P.A. 1973). As indicated, any common understanding of the word "therapeutic" includes pain relief. This is borne out by case law.

In determining the common meaning of the term "therapeutic" for purposes of classifying an article under HTSUS Heading 3004, the court in *Warner-Lambert Co. v. United States*, 341 F. Supp. 2d 1272, 1277 (Ct. Int'l Trade 2004), referred to Stedman's Medical Dictionary, which provides that "therapeutic" is "relating to . . . the treatment, *remediating*, or curing of a disorder or disease." STEDMAN'S MEDICAL DICTIONARY 1821 (27th ed. 2000) (emphasis added). The term "therapeutic" has been defined for tariff purposes as embracing "the alleviative or palliative, as well as the curative or healing qualities." *J.E. Bernard & Co., Inc. v. United States*, 58 Cust. Ct. 23, 28, 262 F. Supp. 434, 438 (1967); *see also id.* at 29 (finding that hearing aids which ease the affection of deafness without curing it are therapeutic devices); *United States v. Alltransport, Inc.*, 44 C.C.P.A. 149, 152 (1957) (a product is a medicinal if it is "of use, or believed by the prescriber or user fairly and honestly to be of use, in curing or alleviating, or palliating or preventing, some disease or affliction of the human frame"). In sum, it is not necessary that a substance cure a disease to be described as "therapeutic."

The definitions of "therapeutic" in *J.E. Bernard* and *Alltransport* are consistent with that in Stedman's Medical Dictionary, and are consistent with the Harmonized System. For example, HTSUS Heading 3003 provides for products with "therapeutic or prophylactic uses" and bulk analgesics such as aspirin and acetaminophen are classified therein. *See* Cust. NY Rul. I80346, 2002 U.S. Cust. NY Lexis 3114, at *1 (April 11, 2002) (classifying acetaminophen under HTSUS subheading 3003.90.0000); Cust. NY Rul. C88562, 1998 U.S. Cust. NY Lexis 5438, at *1 (June 25, 1998) (classifying aspirin under HTSUS subheading 3003.90.0000). Analgesics do not cure disease. They are principally used for pain relief, yet are "therapeutic" for tariff purposes under the Harmonized System.

Defendant relies almost exclusively on one case that, at least superficially, appears to hold to the contrary. *See Richards Med. Co. v. United States*, 13 CIT 519, 522, 720 F. Supp. 998, 1001 (1989), *aff'd*, 910 F.2d 828 (Fed. Cir. 1990). *Richards* involved the classification of certain hip prostheses and instruments. The court described the replacement of the hip joint as a "compensatory remedy of a disability and not a therapy." *Id.* at 522. The case had nothing to do with oral pain relief medications and construed a special duty-free provision under the former tariff scheme, which has now been replaced by the HTSUS. The statute at issue in *Richards* is now part of HTSUS

chapter 98, which contains special provisions that are not part of the Harmonized System itself. *See* HTSUS chapter 98, subchapter XVII, U.S. note 1(a)(i). In fact, while recognizing that the broad meaning of "therapeutic" includes "alleviative," the Court of Appeals in *Richards* emphasized a different specific legislative intent as to the special classification provision, which provision is not at issue here. *Richards Med. Co.*, 910 F.2d at 831. The court finds *Richards*, if it has any continuing validity, to be distinguishable.

The court cannot ignore the ordinary common understanding of the term "therapeutic," the medical definition of the term, Customs' treatment of pain relief medications, defendant's concessions, and the views of witnesses on both sides that pain relief is therapeutic. The court may not, to the contrary, adopt an interpretation from one non-analogous case.

Defendant's other main support is its own ruling, Cust. Rul. 962697, 2000 U.S. Cust. Lexis 656 (June 25, 1998). Defendant relies on that portion of the ruling, which finds that CS is not prepared for a therapeutic use because its efficacy in treating OA pain has not been proven to the degree that the FDA will allow it to be marketed as a drug. *Id*. at *9. While the defendant conceded that final FDA approval is not necessary, *see* Tr. at 417–18,[7] Customs apparently requires "better" studies showing the efficacy of CS than are currently available in order to classify CS under HTSUS subheading 3001.90.00.

The court, however, can find no words in the statute that require conclusive proof of efficacy. The statute merely provides that the product be "prepared for therapeutic or prophylactic uses." HTSUS subheading 3001.90.00. Whether Customs may operate as a mini FDA to exact higher duties on fake curatives is not before the court. CS is not a fake curative or palliative. It is a preparation that some studies, which are accepted by some practitioners, show is useful in relieving OA pain. That view has been accepted in the marketplace and CS preparations are bought for that purpose, and based on the evidence before the court, none other.[8]

Whatever FDA labeling or marketing regulation restricts the manner in which CS preparations are sold does not control for tariff purposes. *See Swift & Co. v. United States*, 2 Cust. Ct. 180, 182 (1939).[9]

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[7] *Guidance Concerning the Tariff Classification of Pharmaceutical Products Imported for Clinical Research*, Customs Bulletin, Vol. 34, No. 21 (May 24, 2000) recognized that substances entering Phase I of the clerical trial process are to be treated as having therapeutic properties. *Id*. at 11–12. CS has had Phase II and Phase III trials. Tr. at 47 (Moskowitz).

[8] Apparently, as there was no evidence that bulk CS is manufactured for use other than in OA treatment preparations, defendant does not rely on proof of non-therapeutic uses.

[9] The Dietary Supplement Health and Education Act ("DSHEA") was intended to ease access to alternative therapies. *See* Senate Report 103–410 at 14–15, *reprinted in*, 1994 USCCAN 3523. Congress seemed to recognize CS-like preparations as therapeutic. *Id*. Accordingly, these preparations were not to be termed "drugs" for FDA purposes so that they could

Further, definitions and classifications of other agencies do not control tariff classifications. *Marubeni Am. Corp. v. United States*, 17 CIT 360, 369, 821 F. Supp. 1521, 1528–29 (1993), *aff'd*, 35 F.3d 530 (Fed. Cir. 1994) (vehicle regulated as a "truck" by other agencies classified for tariff purposes as passenger vehicles).

Tariff classification law relies heavily on commercial practice and understandings. Tariff classifications are mainly about the marketplace. In determining whether a particular item falls within the class or kind of merchandise principally used in the manner described by a tariff heading, the courts have considered the following factors: (1) general physical characteristics; (2) expectations of the ultimate purchaser; (3) channels of trade in which the merchandise moves; (4) environment of sale; (5) use in the same manner as merchandise which defines the class; (6) economic practicality of so using the imported merchandise; and (7) recognition in the trade of this use. *Lenox Collections v. United States*, 19 CIT 345, 347 (1995); *United States v. Carborundum Co.*, 536 F.2d 373, 377 (C.C.P.A. 1976). By application of these factors to the CS at issue, the overwhelming weight of the evidence points to CS belonging to the class or kind of merchandise described in HTSUS Heading 3001.

Because it is an animal substance manufactured at a relatively high level of purity sold in the form of pills, tablets, or capsules from bulk powder, similar to bulk aspirin, CS has the physical characteristics of the class or kind of products covered by HTSUS Heading 3001. As indicated, the marketing of the products and expectations of its purchasers center on the pain relief potential of CS. CS products are marketed and sold in the same manner as over-the-counter drugs, including directly to doctors, even if they are often displayed with dietary supplements and vitamins for FDA reasons. Thus, the channels of trade and environment of sale are consistent with products classifiable under HTSUS Heading 3001.

As indicated, CS is prepared for use as, and is actually used as, an OA treatment. That seems to dictate the "economic practically" of such use, as it is the only current use for CS and obviously, the trade recognizes such use. Thus, all of the *Carborundum* factors are met for classification of CS under plaintiff's claimed classification 3001.90.00.

In conclusion, the court is not required to determine how effective CS is as an OA pain reliever. It is enough that the marketplace recognizes CS as a therapeutic substance. The court cannot function as a substitute FDA. If at some point CS is shown to be ineffective, the market for it as an OA pain reliever will cease to be. Until that time, there is enough evidence of efficacy so that a substantial portion of

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be made more widely available. Customs ruling turns the law on its head by relying on DSHEA to deem CS non-therapeutic.

the medical community views it as efficacious, and so that the court must conclude CS is prepared for, marketed for, sold and bought for a therapeutic use.[10]

Plaintiff's primary classification claim under HTSUS subheading 3001.90.00 is sustained. Judgment will enter accordingly.

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[10] Because a use provision will prevail over a general provision such as plaintiff's alternative, HTSUS subheading 0410.00.00, edible animal products, this classification is not considered.