SLIP OP. 05-48

UNITED STATES COURT OF INTERNATIONAL TRADE

INABATA SPECIALTY CHEMICALS,	:	
Plaintiff,	:	
	:	Court No. 01-00600
v.	:	
UNITED STATES,	:	
Defendant.	:	

[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 modified 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

[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).

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, 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

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

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

[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.

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 (analyses 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

[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.

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 importation, 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] Further, definitions and classifications of other agencies do not control tariff classifications. Marubeni Am. Corp. v. United States, 17 CIT 360, 369, 821 F.

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

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 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.

/s/ Jane A. Restani
Jane A. Restani
CHIEF JUDGE

Dated: New York, New York
This 13th day of April, 2005.

[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.