UNITED STATES COURT OF INTERNATIONAL TRADE

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WARNER-LAMBERT COMPANY, :

Plaintiff, :

v. : Court No. 01-00056

UNITED STATES, :

Defendant. :

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Opinion

[Upon trial as to the classification of **HALLS DEFENSE™** *Vitamin C Supplement Drops*, judgment for the defendant.]

Decided: June 21, 2004

Rode & Qualey (Patrick D. Gill) for the plaintiff.

Peter D. Keisler, Assistant Attorney General; Barbara S. Williams, Attorney-in-Charge, International Trade Field Office, Commercial Litigation Branch, Civil Division, U.S. Department of Justice (Bruce N. Stratvert); and Office of Assistant Chief Counsel, International Trade Litigation, U.S. Bureau of Customs and Border Protection (Beth C. Brotman), of counsel, for the defendant.

AQUILINO, Judge: This action has been designated a test case within the meaning of USCIT Rule 84(b). It contests revocation of U.S. Customs Service letter NY 832151 (Sept. 21, 1988), which ruled that "Halls Vitamin C Drops" be classified under the tariff schedules of the United States as medicament. In HQ 958150 (April 7, 1998), however, the Service, which is now known as Customs and Border Protection, U.S. Department of Homeland Security,

came to conclude that the British merchandise at bar as plaintiff's trial exhibit 1, **HALLS DEFENSE™** *Vitamin C Supplement Drops*, is sugar confectionery, classifiable under heading 1704 of the Harmonized Tariff Schedule of the United States ("HTSUS").

The subheading thereunder, 1704.90.35, pursuant to which duties at rates of 6.1 and 5.8 percent *ad valorem* have been collected, depending upon year of entry, appears in the HTSUS as follows:

> Sugar confectionery (including white chocolate), not containing cocoa:
> Chewing gum, whether or not sugar-coated.....
>
> Other:
> Confections or sweetmeats ready for consumption:
> Candied nuts.....
>
> Other:
> Cough drops.....
>
> 1704.90.35 Other.....[.]

During the decade that letter NY 832151 ruled Customs, the HTSUS had come to provide duty-free entry for Halls drops under subheading 3004.50.5010, to wit:

> Medicaments . . . consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale:
>
> * * *
>
> Other medicaments containing vitamins or other products of heading 2936:

* * *

Other:.....

* * *

Other:
Single vitamins:
Combined with minerals or other nutrients.....[.]

And the plaintiff prays for return to classification of its goods thereunder.[1]

I

The court's jurisdiction is based upon 28 U.S.C. §§ 1581-(a), 2631(a). Trial was conducted pursuant to a pretrial order that set forth the following uncontested facts, among others:

> 2. . . . [T]he merchandise in issue . . . [is] packaged in lozenge form [and] sold in . . . flavors described as "ASSORTED CITRUS" and . . . as "STRAWBERRY".

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[1] In doing so, the plaintiff abandons an alternative claim that its drops are classifiable under HTSUS subheading 2936.27.00 ("Vitamin C (Ascorbic acid) and its derivatives"). See Pretrial Order, Schedule C, para. 17; Plaintiff's Proposed Findings of Fact and Conclusions of Law [hereinafter referred to as "Plaintiff's Brief"], p. 10.

The court notes in passing the absence of any claim herein that the goods at issue are "Cough drops" within the meaning of HTSUS subheading 1704.90.25, supra, because Additional U.S. Note 11 states that, for purposes of that subheading, such drops

> must contain a minimum of 5 mg per dose of menthol, of eucalyptol, or of a combination of menthol and eucalyptol[,]

which requirement is not met in this matter. See Pretrial Order, Schedule C, paras. 3, 4, 12; and note 4, infra.

3. The . . . ingredients in the assorted citrus flavor [are] approximately as follows: Sugar 51.80%, Glucose Syrup 44.20%, Sodium Ascorbate (Vitamin C) 1.69%, Citric Acid 1.83%, Natural flavors (orange, lemon, sweet grapefruit & menthol) 0.26%, Asorbic [*sic*] Acid (Vitamin C) 0.22%, Colors (FD&C Red No. 40 and B-carotene) 0.01%.

4. The . . . ingredients in the strawberry flavor [are] approximately as follows: Sugar 52.27%, Glucose Syrup 44.57%, Sodium Ascorbate (Vitamin C) 1.69%, Citric Acid 1.00%, Ascorbic Acid (Vitamin C) 0.22%, Natural & Artificial Flavors (strawberry & menthol) 0.21%, Colors (Carmine) 0.04%.

5. Each . . . drop (lozenge) contains 60 milligrams of Vitamin C.

6. 60 milligrams is the current recommended daily value of Vitamin C as set by the United States Food and Drug Administration . . . .

7. Vitamin C prevents scurvy.

8. Scurvy is the disease caused by the lack of Vitamin C.

9. Human beings, unlike many other mammals, are unable to make their own Vitamin C[] and therefore[] must meet their Vitamin C needs from external sources.

10. The Vitamin C in the imported Halls . . . drop[s], Sodium Ascorbate and Ascorbic Acid, is combined with other nutrients; namely, sugar, glucose syrup and citric acid.

11. Vitamin C is an important part of daily nutrition in that it maintains health and well being.

12. The average menthol content in the drops[] in issue[] is 0.025 percent.

13. The merchandise[] in issue[] is a dietary supplement, as defined by DSHEA [Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417] and FDA regulations.

14. The molecular formula for ascorbic acid is $C_6H_8O_6$, and the molecular formula for sodium ascorbate is $C_6H_7NaO_6$.

15. The imported product contains two forms of Vitamin C.

16. The imported merchandise is not marketed as preventing or curing any disease.

Examination by the court of plaintiff's merchandise, exhibit 1, shows it to be approximately three quarters of an inch square by some three-and-one-half inches long, wrapped in such manner as to display **HALLS DEFENSE™** *Vitamin C Supplement Drops* on contiguous side panels to the left of "100% Daily Value of Vitamin C in each drop" and "9 DROPS", to the right of which references are the words "ASSORTED CITRUS" and "ALL NATURAL FLAVORS" imprinted on a green banner superimposed upon what apparently are intended to be likenesses of a grapefruit, lemon and orange. A third side panel specifies the ingredients of each, the name and address of its corporate distributor, the country of origin, and a chart of "Supplement Facts", including percentages of certain "Daily Values" in addition to vitamin C. The fourth wrapper panel is stamped with a code number and a bar code plus the following prose:

> Halls Defense Vitamin C Supplement Drops help keep you going, because each drop delivers 100% of the Daily Value of Vitamin C. So now, your family can soothe their throats with delicious, fruit flavored drops while getting the Vitamin C they need. Assorted Citrus Halls Defense Vitamin C Supplement Drops are available in the following all natural flavors: Lemon, Sweet Grapefruit, and Orange. Assortment in each package may vary. 100% Daily Value of Vitamin C in each drop.

In sum, the thrust of plaintiff's product, on its face, is that

vitamin[2], which this court notices has been the subject of much scientific ergo commercial discourse.

Based upon the record adduced herein, the court can find that the availability of vitamin C in various forms and substances has relegated one of the oldest nutritional disorders of mankind, scurvy, to a low rung of medical concern. The same cannot be said for many other, such concerns *vis-à-vis* vitamin C. Nonetheless, studies have concluded that that vitamin may help forestall maladies such as cancer, cardiovascular deterioration, cataracts, pulmonary disease, although at least some of those studies have been carried out in conjunction with vitamin E, making it difficult to define the precise therapeutic or prophylactic properties of the C vitamin itself. What is known, and was confirmed at the trial, is that some oxygen is metabolized within the human body into "free radicals" that are

> highly reactive, toxic molecules, and the body has evolved some endogenous, defensive mechanisms, enzymes, to combat these toxic products but also relies very much on dietary factors such as essential vitamins like . . . C and . . . E . . . to combat the toxic effects of these metabolites.

Tr., p. 15. In other words, vitamin C "functions physiologically as a water-soluble antioxidant by virtue of its high reducing power." Defendant's Exhibit A (Institute of Medicine, Dietary Ref-

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[2] At the trial, plaintiff's product manager characterized the fact of 100 percent of the daily value of vitamin C as "a very compelling claim from a consumer standpoint". Transcript ("Tr."), p. 129. See generally id. at 129-33.

erence Intakes (DRI) for Vitamin C, Vitamin E, Selenium, and Carotenoids), p. 95 (2000). This antioxidant property is the basis of vitamin C's recommended dietary allowance ("RDA")[3], which is the

> dietary intake level that is sufficient to meet the nutrient requirement of nearly all (97 to 98 percent) healthy individuals in a particular life stage and gender group.

Id. at 3. This allowance has not been set as a result of any therapeutic or prophylactic properties. Compare Tr., pp. 78-79, with id. at 119-21. In fact, the studies with regard thereto often entail doses of vitamin C in excess of the RDA. See, e.g., id. at 84.

II

The Customs letter HQ 958150 that overruled the Service's earlier ruling as to plaintiff's merchandise states in part:

> In NY 832151, Customs classified HVCDs in subheading 3004.50.5010, HTSUS, based upon the belief that Vitamin C imparted therapeutic or prophylactic character to the merchandise. Additional research indicates that Vitamin C has not been shown in the U.S. to have substances which imbue it with therapeutic or prophylactic properties or uses. Therefore, HVCDs are not classifiable as medicaments of chapter 30, HTSUS, and NY 832151 must be revoked.
>
> At its Eleventh Session on September 16, 1993, the Harmonized System Committee . . . greatly limited the list of ingredients which are considered to possess "therapeutic or prophylactic" value. This change was adopted in the form of two amendments to the ENs . . ..

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[3] See, e.g., id. at 78-79; Defendant's Exhibit A, pp. 12, 95.

> . . . [T]he Vitamin C contained in HVCDs is akin to other common lozenge additives which seem to possess curative properties, but do not satisfy the new, higher standard for "therapeutic or prophylactic" goods.
>
> Additionally, EN 30.04[] states . . . that:
>
> > This heading includes pastilles, tablets, drops, etc., of a kind suitable **only** for medicinal purposes, such as those based on sulphur, charcoal, sodium tetraborate, sodium benzoate, potassium chlorate or magnesia. However, preparations put up as throat pastilles or cough drops, consisting essentially of sugars (whether or not with other foodstuffs such as gelatin, starch or flour) and flavouring agents (including substances having medicinal properties, such as benzyl alcohol, menthol, eucalyptol, and tolu balsam) . . . fall in **heading 17.04**.
>
> Pastilles, tablets, or drops, suitable only for medicinal purposes, are normally dispensed with a doctor's prescription, or are only purchased with the intention of curing an ailment. HVCDs are sold in a variety of stores together with other sugar-confectionary products "over the counter" without a prescription. Therefore, Customs remains of the opinion that the merchandise is classifiable in heading 1704, HTSUS.[4]

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[4] Defendant's Exhibit T, p. 4 (boldface in original). "HVCDs" and "EN" refer respectively to plaintiff's product and to Explanatory Note(s) to the HTSUS. This ruling letter further states:

> The decision in NY 832151 was based on Customs belief that HVCDs had therapeutic or prophylactic properties. Since this is not the case, the merchandise cannot be classified in chapter 30, HTSUS. Likewise, the presence of sugars, flavorings and colorings renders them ineligible for classification in chapter 29, HTSUS. Therefore, HVCDs are classifiable as sugar confections of chapter 17, HTSUS. The lack of menthol, eucalyptol, or a combination thereof in the merchandise prevents its classification in subheading 1704.90.25, HTSUS. Sugar-based drops containing Vitamin C, but no menthol or eucalyptol, are therefore classifiable in the basket provision, subheading 1704.90.35, HTSUS . . . .

Id. at 6.

A

A Customs ruling like the foregoing "is eligible to claim respect according to its persuasiveness", United States v. Mead Corp., 533 U.S. 218, 221 (2001), citing Skidmore v. Swift & Co., 323 U.S. 134 (1944), based on "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." 323 U.S. at 140. Moreover, factual findings underlying a Customs classification are presumed by 28 U.S.C. §2639(a)(1) to be correct[5], thereby placing the burden of proof upon the party protesting it. See, e.g., Rollerblade, Inc. v. United States, 282 F.3d 1349, 1352 (Fed. Cir. 2002).

Judicial review of a classification is a two-step process in which the court determines the meaning of the relevant tariff terms and whether the merchandise in question satisfies that meaning. E.g., id. at 1352, citing Sports Graphics, Inc. v. United States, 24 F.3d 1352, 1391 (Fed.Cir. 1994). The General Rules of Interpretation ("GRI") and the Additional U.S. Rules of Interpretation ("ARI") of the HTSUS are an element of this review process. See, e.g., Carl Zeiss, Inc. v. United States, 195 F.3d 1375, 1379 (Fed.Cir. 1999). See also Rollerblade, Inc. v. United States, 282 F.3d at 1351-52. Specifically, GRI 1 provides that "classification

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[5] See, e.g., Universal Electronics Inc. v. United States, 112 F.3d 488, 491-92 (Fed.Cir. 1997).

shall be determined according to the terms of the headings and any relative section or chapter notes". See, e.g., Orlando Food Corp. v. United States, 140 F.3d 1437, 1440 (Fed.Cir. 1998). Furthermore, a "use" provision, which "describ[es] articles by the manner in which they are used as opposed to by name"[6], is guided by ARI 1-(a) to the effect 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[.]

See, e.g., Primal Lite, Inc. v. United States, 182 F.3d 1362, 1363 (Fed.Cir. 1999).

On its face, HTSUS heading 3004, supra, is such a provision. Cf. HQ 964673 (Feb. 4, 2002).

(1)

The use contemplated by that heading is "therapeutic or prophylactic", the meaning of which this court must now determine. See, e.g., Universal Electronics Inc. v. United States, 112 F.3d 488 (Fed.Cir. 1997):

> . . . Questions of law such as [the proper interpretation of a particular tariff provision or term] lie within the domain of the courts, for "[i]t is emphatically the province and duty of the judicial department to say what the law is."

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[6] Len-Ron Mfg. Co. v. United States, 334 F.3d 1304, 1308 (Fed. Cir. 2003).

112 F.3d at 492, quoting Marbury v. Madison, 5 U.S. 137, 177 (1803). Absent a definition in the HTSUS, those terms are to be defined according to their common meaning, provided that such meaning is consistent with legislative intent. See, e.g., Lonza, Inc. v. United States, 46 F.3d 1098, 1106 (Fed.Cir. 1995), citing Nippon Kogaku (USA), Inc. v. United States, 69 CCPA 89, 92, 673 F.2d 380, 382 (1982). See also Schott Optical Glass, Inc. v. United States, 67 CCPA 32, 34, 612 F.2d 1283, 1285 (1979); Carl Zeiss, Inc. v. United States, 195 F.3d at 1379. To determine common meaning, the court "may consult dictionaries, lexicons, scientific authorities, and other such reliable sources". Lonza, Inc. v. United States, 46 F.3d at 1106, citing C.J. Tower & Sons of Buffalo, Inc. v. United States, 69 CCPA 128, 133-34, 673 F.2d 1268, 1271 (1982).

The term "therapeutic" is defined in Stedman's Medical Dictionary, page 1587 (25th ed. 1990), as "[r]elating to therapeutics or to the treatment of disease". Webster's Third New International Dictionary Unabridged, page 2372 (1981), defines the term as "of or relating to the treatment of disease or disorders by remedial agents or methods: CURATIVE, MEDICINAL". Consistent with these definitions, the court in Richards Medical Co. v. United States, 13 CIT 519, 521, 720 F.Supp. 998, 1000 (1989), aff'd, 910 F.2d 828 (Fed.Cir. 1990), for example, accepted therapeutic as "having healing or curative powers".

Stedman's Medical Dictionary, page 1268, defines "prophylactic" as "1. Preventive; preventing disease; relating to prophylaxis. 2. An agent that acts to prevent a disease." That term is defined by Webster's Third New International Dictionary Unabridged on page 1818 as "guarding from disease: preventing or contributing to the prevention of disease".

The plaintiff contends that its drops have

> prophylactic or therapeutic uses in the prevention or cure of, *inter alia*, the following diseases: scurvy, cancer, pulmonary and cardiovascular disease, cataracts, diabetes, osteoporosis, periodontal disease, hypertension, reduction of mortality, and diseases and illnesses associated with the reproductive function as well as the cognitive and immune functions.

Pretrial Order, Schedule C-1, para. 2. In support, it relies primarily on the opinion of its expert, the Associate Director of the U.S. Department of Agriculture's Human Nutrition Research Center on Aging at Tufts University, Professor Jeffrey Blumberg, Ph.D., F.A.C.N., C.N.S. It produced at the trial both him and his report(s) entitled Scientific Substantiation of the Benefits of Vitamin C on Vitality and Well-Being (Sept. 1998) and Scientific Substantiation of the Benefits of Vitamin C on Vitality and Well-Being[,] An Update of the Scientific Literature (July 1998-December 2001) (Jan. 2002), received in evidence together as plaintiff's exhibit 2.

The defendant challenges the epidemiological nature of this analysis, its expert taking the position at trial that such

an approach seeks "associations" and "cannot lead to a definition of cause and effect".[7] The defendant cites no law that stands for

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[7] Tr., p. 253. See Defendant's Exhibit B [Report of Robert E. Olson, M.D., Ph.D.], p. 17 ("I am not impressed with the results of the epidemiologic data which Dr. Blumberg quotes since they represent associations but not proof of cause and effect").

The plaintiff objected to admission into evidence of this exhibit B. First, it argued that this report fails to comply with USCIT Rule 26(a)(2)(B) in that the defendant was "required to indicate the compensation paid to the Witness." Tr., p. 237. Counsel also claimed that portions of the report are legal argument and views that have little bearing on the scientific expertise of Dr. Olson and thus violate the standards set forth in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). See id.; Plaintiff's Brief, p. 8.

The court reserved decision. It now concludes that plaintiff's second claim has merit; the first does not. USCIT Rule 37-(c)(1) states:

> A party that without substantial justification fails to disclose information required by Rule 26(a) . . . is not, unless such failure is harmless, permitted to use as evidence . . . any witness or information not so disclosed.

While true that Dr. Olson's compensation is not disclosed in his report, the plaintiff was notified thereof prior to its production. See Tr., p. 238. Thus, defendant's approach did not prejudice the plaintiff and does not require exclusion of the report under the foregoing rule. See, e.g., Norbrook Labs. Ltd. v. G.C. Hanford Mfg. Co., 297 F.Supp.2d 463, 481 (N.D.N.Y. 2003) ("Failure to comply with the mandate of [Rule 37] is harmless when there is no prejudice to the party entitled to the disclosure"), quoting Nguyen v. IBP, Inc., 162 F.R.D. 675, 680 (D.Kan. 1995).

To accept testimony as expert, the court must find that it is based on "scientific knowledge" and "will assist the trier . . . to understand a fact in issue". Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. at 589-90, 592. See also Meister v. Med. Eng'g Corp., 267 F.3d 1123, 1126 (D.C.Cir. 2001); Federal Rule of Evidence 702 (2000):

(footnote continued)

the proposition that evidence of cause and effect must be presented in order to draw scientific conclusions, nor has the court found

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> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise . . . .

The Court in Daubert stressed that "the adjective 'scientific' implies a grounding in the methods and procedures of science". 509 U.S. at 589-90. Paragraphs 9-12 of defendant's exhibit B, which characterize the history of this action and also the law, are inadmissable as not within the scope of the scientific expertise of Dr. Olson. See, e.g., Wheeling Pittsburgh Steel Corp. v. Beelman River Terminals, Inc., 254 F.3d 706, 715-16 (8th Cir. 2001):

> . . . Once initial expert qualifications and usefulness . . . are established, . . . a [trial] court must continue to perform its gatekeeping role by ensuring that the actual testimony does not exceed the scope of the expert's expertise, which if not done can render [the] testimony unreliable under Rule 702, *Kumho Tire*, and related precedents.

In this action, an expert is to provide opinion that may be helpful in determining the nature of the merchandise and any therapeutic or prophylactic properties or uses. Attempted recital of the case history, including an incorrect summary of the parties' arguments and an interpretation of the law, does not advance that objective.

While the plaintiff broadly invokes the "standards" of Daubert, the court need not delve into the reliability factors for which that case stands. The inquiry here pertains to the scope of expert testimony under Rule 702, supra, which "clearly contemplates some degree of regulation of the subjects and theories about which an expert may testify". 509 U.S. at 589. Finding that paragraphs 9-12 of Dr. Olson's report must be disregarded, resort to those factors is unnecessary. See, e.g., Libas, Ltd. v. United States, 193 F.3d 1361, 1367 (Fed.Cir. 1999):

> . . . There is no iron law that the *Daubert* factors be applied in Customs classification cases. The Court of International Trade obviously need not use them in every case, or even in most such cases. These factors are primarily applicable when the question involves a technical process where the reliability of a scientific or technical methodology has been raised as an issue.

any. While proof of cause and effect is an element of toxic tort actions[8], for example, it is not required in a matter like this. Rather, the plaintiff at bar can overcome the presumption of correctness with a preponderance of the evidence, "the greater weight of evidence, evidence which is more convincing than the evidence which is offered in opposition to it". St. Paul Fire & Marine Ins. Co. v. United States, 6 F.3d 763, 769 (Fed.Cir. 1993), quoting Hale v. Dep't of Transportation, 772 F.2d 882, 885 (Fed. Cir. 1985).

Scientific evidence need not be compelling, definitive, conclusive, or cause-and-effect certain. In upholding an administrative decision to promulgate regulations reducing the lead content in gasoline, for example, the court in Ethyl Corp. v. EPA, 541 F.2d 1, 37-38 (D.C.Cir. 1976), stated:

> . . . [W]e need not seek a single dispositive study that fully supports the Administrator's determination. Science does not work that way . . . . [T]he Administrator's decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies. By its nature, scientific evidence is cumulative: the more supporting, albeit inconclusive, evidence available, the more likely the accuracy of the conclusion.

See also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. at 590 ("it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science" (citations omitted)); Hodges

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[8] See, e.g., Raynor v. Merrell Pharmaceuticals Inc., 104 F.3d 1371 (D.C.Cir. 1997).

v. Sec'y of Dep't of Health & Human Services, 9 F.3d 958, 966-67 (Fed.Cir. 1993)("The statutory standard of a simple preponderance of evidence precludes the imposition of the standard of scientific certainty" (citation omitted)); LeFevre v. Sec'y, Dep't of Veterans Affairs, 66 F.3d 1191, 1199 (Fed.Cir. 1995)("The standard for determining whether a positive association exists is whether the 'credible evidence' for the association equals or outweighs the credible evidence against it"). Hence, to the extent that defendant's expert is opining about the value of epidemiological research to prove or disprove scientific theory, his criticism misses the mark.

If, however, defendant's critical stance is not just general disagreement, but derives from the standard governing heading 3004, it comes closer to the point. Though not exactly cause and effect, this court understands that heading as requiring that a substance have some recognizable "medicinal" impact. The Explanatory Notes to heading 3004 state that

> [t]hroat pastilles or cough drops containing substances having medicinal properties . . . remain classified in this heading . . . **provided** that the proportion of those substances in each pastille or drop is such that they are thereby given therapeutic or prophylactic uses.[9]

Though not binding, such notes are instructive with regard to tariff provisions. E.g., Mita Copystar America v. United States, 21 F.3d 1079, 1082 (Fed.Cir. 1994), citing Lynteq, Inc. v. United

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[9] Emphasis in original. The Explanatory Notes to heading 1704 complement those to 3004 with similar reasoning.

States, 976 F.2d 693, 699 (Fed.Cir. 1992). The significance of a connection between a dose and therapeutic or prophylactic properties also finds support in the body of the HTSUS itself. To be classified in heading 3004, qualifying medicaments must be "put up in measured doses or in forms or packings for retail sale". Again, resort to the explanatory notes provides guidance and affirms the importance of maintaining the substances "ready for taking as single doses for therapeutic or prophylactic use" or, alternatively, in a packing where because of the "presence of appropriate indications (. . . statement of dose, etc. . . .) [the products] are clearly intended . . . for [therapeutic or prophylactic] purposes."

In short, dosage cannot be separated from therapeutic or prophylactic properties. A measured dose is not merely a certain amount; it should contemplate an effect therefrom. Hence, the dose must be viewed as a way to link the properties of a substance with that effect. Here, the plaintiff must show that a specific quantity of vitamin C, e.g., 60 milligrams per day, can help prevent disease. It would make little sense to classify a product as a medicament merely because of a vitamin content without first finding that that particular content could or does precipitate the therapeutic or prophylactic properties contemplated by heading 3004. Indeed, the use provision guards against that.

In this action, the role of vitamin C in treating and preventing scurvy is uncontested. That that malady is of little moment now in this land of fruits and imports does not diminish that therapeutic and prophylactic phenomenon. As for the numerous other diseases that are not yet under such control, at the trial plaintiff's expert seemingly chose his words carefully, for example: "there's a number of epidemiological studies showing . . ." [cancer] Tr., p. 18; "there has been a remarkably consistent body of evidence showing . . ." [cataracts] id. at 19; "there are a number of studies. . ." [pulmonary disease and function] id. at 23; "there actually have been a number of clinical trials showing" [hypertension] id. at 21. This stands in contrast to other qualified language to describe the strength of studies examining other diseases, e.g., the evidence is "not so direct" [diabetes] id. at 20; there were "really just a few studies" [mortality] id.; "a very limited number of studies" [bone health] id. at 22.

On his part, defendant's expert generally sought to disagree that vitamin C has therapeutic or prophylactic properties[10], but without conclusive success. In fact, defendant's own exhibit A, the Institute of Medicine's Dietary Reference Intakes

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[10] Dr. Olson testified, for example, that the evidence concerning vitamin C's therapeutic or prophylactic properties is "unproven", that he was "not impressed with the results of the epidemiologic data which Dr. Blumberg quotes", and that he "disagree[s] that the data available permit[Dr. Blumberg']s conclusion". Tr., p. 211; Defendant's Exhibit B, pp. 17-18.

(DRI) for Vitamin C etc., supports the view that studies examining cardiovascular disease, cancer, cataracts, and asthma and obstructive pulmonary disease "suggest a protective effect of Vitamin C".[11] Affirming this view, Dr. Olson himself conceded that plaintiff's studies were "suggestive"[12] and thus compatible with the standard enunciated hereinabove.

Whatever the evidence as to vitamin C *per se*, the issue herein is whether goods containing that vitamin, but mostly sugar and glucose syrup, have therapeutic or prophylactic properties. The defendant argues that, of

> the 107 publications cited by Dr. Blumberg, only 49 employ only vitamin C as the agent for study. The majority of the papers 58 (54%) involve other antioxidants in addition to vitamin C (vitamin E, carotinoids and selenium).

Defendant's Exhibit B, p. 16. See also Tr., p. 60. In addition, the defendant points out that many of the studies focus on quantities of vitamin C that far exceeded the amount found in the Halls drops. See id. 84.

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[11] Defendant's Exhibit A, pp. 122, 125-26. The Institute of Medicine was unable to reach that point for any of the other chronic diseases under study.

[12] Tr., p. 260:

> . . . I will say the whole field . . . put forth by the Plaintiff is suggestive data not compelling data. It is suggestive, but it has not stood the test of scientific rigor that requires that it be tested experimentally and in clinical studies, and it yields such positive results that it is compelling.

Id.

This court's understanding of HTSUS heading 3004 is that there must be a connection between a dosage and any therapeutic or prophylactic effect therefrom. To this end, and thus to link the properties of vitamin C in the abstract with those of the drops at issue, the plaintiff relies on the fact that each contains 100 percent of the daily value. But that value is not shown on the record developed to cure or prevent disease other than scurvy. The facts, as presented on both sides, simply do not support a grander finding. The Food and Nutrition Board, which helps set the RDA[13], found that even the studies suggestive of an association between vitamin C and therapeutic or prophylactic properties were of limited utility in the derivation of an appropriate vitamin C intake level because,

> [a]lthough many of the [] studies suggest a protective effect of vitamin C . . ., the data are not consistent or specific enough to estimate a vitamin C requirement . . ..

Defendant's Exhibit A, pp. 122, 125-126. Plaintiff's expert confirmed this inability to link a particular dose with a therapeutic or prophylactic effect:

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[13] Though not interchangeable, the terms daily value and recommended dietary allowance are both relevant to the facts of this action. While that allowance sets an intake level for a particular life stage and gender group, the daily value averages levels. In addition, reference is made to the DRI, which are the focus of defendant's exhibit A. This approach provides a new method for quantitative estimates of nutrient intakes, which include the Recommended Dietary Allowance, in addition to the Adequate Intake, the Tolerable Upper Intake Level, and the Estimated Average Requirement. See Defendant's Exhibit A.

> . . . What I'm merely saying is that the scientific studies show that there is an association of benefit from increasing Vitamin C intakes. . . .
>
> [T]here's a benefit for Vitamin C, but I am unable, as was the Food and Nutrition Board, . . . to make a quantitative decision on what the dose would be. Part of that is the challenge that there are a lot of different diseases, and it's very likely that the doses needed in each case might be different.

Tr., p. 119.

(2)

Be this inability as it is, were this court to find plaintiff's product to be a medicament (at least because of scurvy), the issue remains whether or not that is its principal use:

> The purpose of "principal use" provisions in the HTSUS is to classify particular merchandise according to the ordinary use of such merchandise . . ..

Primal Lite, Inc. v. United States, 182 F.3d 1362, 1364 (Fed.Cir. 1999). That has been defined as the "predominant use, rather than simply one possible use"[14] and the "use which exceeds any other *single* use". Lenox Collections v. United States, 20 CIT 194, 196 (1996) (italics in original). The Explanatory Notes to heading 3004 suggest an even more stringent standard. They state that "heading [3004] includes pastilles, tablets, drops, etc., of a kind suitable **only** for medicinal purposes" (emphasis in original).

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[14] Len-Ron Mfg. Co. v. United States, 334 F.3d 1304, 1311 (Fed.Cir. 2003).

Whatever the definition, the plaintiff has failed to bear its burden. The following factors have been considered to ascertain the nature of goods:

> (1) the general physical characteristics of the merchandise; (2) the expectation of the ultimate purchasers; (3) the channels, class or kind of trade in which the merchandise moves; (4) the environment of the sale (*i.e.*, accompanying accessories and the manner in which the merchandise is advertised and displayed); (5) usage, if any, in the same manner as merchandise which defines the class; (6) the economic practicality of so using the import; and (7) the recognition in the trade of the use.

Minnetonka Brands, Inc. v. United States, 24 CIT 645, 651-52, 110 F. Supp. 2d 1020, 1027 (2000), citing United States v. Carborundum Co., 63 CCPA 98, 102, 536 F.2d 373, 377 (1976). The plaintiff did not offer evidence as to five of them, namely, those numbered (2), (3), (5), (6) and (7).[15] Rather, it relied almost exclusively on the labelling and marketing of the drops within the ambit of factor number four.[16]

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[15] In fact, the only evidence as to this last factor was offered by the defendant, namely, a manufacturer's invoice for an entry at issue in this action referring to the goods as "VIT C confectionary". Tr., p. 150. See id. at 150-54.

Although invoice descriptions are not controlling for classification purposes, they are "evidence which can aid the Court in reaching the proper classification." North American Processing Co. v. United States, 22 CIT 55, 58 (1998), citing Peterson Electro Musical Products v. United States, 7 CIT 293, 295 (1984)(they "are evidence of what the parties, and presumably, the commercial world, consider the merchandise to be").

[16] Although the general physical characteristic of the merchandise, its lozenge form, is consistent with classification as a medicament, that configuration does not foreclose other intake.

As described in part I above, in addition to vitamin C, the packaging of plaintiff's product, exhibit 1, refers to "help keep you going", to the ability to soothe throats, and to all natural fruit flavors. Given these messages, plaintiff's product manager testified that the product is not marketed with any use in mind, leaving that decision to the consumer:

> Q When you market this product to the consumer, do you leave it to the consumer to decide what benefits he or she wants from the product?
>
> A Absolutely.
>
> Q Do you let the consumer decide rather than pushing a specific remedy yourself?
>
> A Yes, we do, and the reason we do is to create the most ubiquitous appeal. By pigeon-holing ourselves into different areas, it just doesn't make sense. It makes more sense in terms of trying to sell the most product to allow consumers to decide for themselves why they want Vitamin C. We just kind of really market this as Vitamin C and allow them to decide why they want it.

Tr., p. 133.

The court must decide whether this approach, combined with the words and symbols on the drops package, circumscribe a medicament for use to treat or prevent at least scurvy. It cannot do so. Even if the court were to find that the Halls lozenges are marketed as vitamin C, it could not, without more, interpret that to mean that they are principally for therapeutic and prophylactic use -- to treat or prevent disease. To so decide on this record

would be to find that vitamin C has become synonymous with such use. Neither the record nor the reference to 100 percent of the daily value of vitamin C establishes such synonymity. Moreover, while the better-educated consumer might understand the significance of that value, such individual understanding itself could not constitute principal use.

The other package references provide different indications of use. First, the soothing of throats is not derived from the vitamin C. See, e.g., Tr., pp. 89-90 ("Most likely Vitamin C contributes little to nothing to the throat-soothing properties of the lozenge"). Rather, that phenomenon is due to the sugar content. See id. at 89. Hence, the packaging of the drops clearly encourages a use of the merchandise not founded on their vitamin C and that has no connection to any therapeutic or prophylactic properties associated therewith.

Second, to "help keep you going" is too vague to project any particular, principal use. While that kind of assistance might derive from the intake of vitamin C in some way, such sensation would understandably be outside the parameters of "therapeutic or prophylactic" as defined by the Explanatory Notes to heading 3004:

> [T]his heading **excludes** food supplements containing vitamins or mineral salts which are put up for the purpose of maintaining health or well-being but have no indication as to use for the prevention or treatment of any disease or ailment.

Emphasis in original. On this point, the court concurs with the position articulated by Customs in HQ 964188 (April 3, 2002):

> Although no clear criteria is [*sic*] provided in either the tariff text or the ENs to differentiate products which are medicinal preparations from those which are designed to maintain general health and well-being, there is a definite distinction made between them.

This is supported by H. Reisman Corp. v. United States, 17 CIT 1260 (1993), appeal dismissed, 39 F.3d 1195 (Fed.Cir. 1994), wherein the court concluded that a substance for mixing vitamin B-12 into animal feed is not a medicament for purposes of heading 3003.90.00, finding that

> the merchandise is not used in a therapeutic or prophylactic manner beyond the purposes provided by any nutrient, including ordinary grain food or food of any kind.

Another explanatory note with regard to HTSUS heading 3004 states:

> On the other hand, the heading covers preparations in which the foodstuff or the beverage merely serves as a support, vehicle or sweetening agent for the medicinal substances . . . .

Cf. Tr., pp. 39-40. Before concluding that the Halls drop is a vehicle for vitamin C's therapeutic or prophylactic properties, however, it must have been proven that the product's principal use is for its vitamin C content and for the properties associated therewith. This, the plaintiff has failed to do.

Third, drawing attention to taste and flavor also tends to expand the use of the drops more than the reference to vitamin C content might tend to limit it. Of course, the goods can be "delicious" or "fruit flavored", but, absent record evidence of principal use for therapeutic or prophylactic purposes, those references distend plaintiff's preferred finding. That is, if the packaging were permitted to, and did in fact, refer to scurvy, with indication of treatment or prevention thereof, then references to gustatory sense could more easily be considered as ancillary.

Here, however, Halls consumers have packaged, printed inducements that do not pinpoint classification under HTSUS heading 3004, e.g., ingest the lozenges for the vitamin C, but not as that substance relates to therapeutic or prophylactic properties; soothe thy self for reasons not associated with that vitamin; or swallow the drops for reasons not yet substantiated by science or proven in this test case.

III

In conclusion, many substances have medicinal properties. Not all of them, however, are medicaments within the meaning of heading 3004. Here, the plaintiff has failed to satisfy its burden of proving that the principal use of its Halls drops corresponds to their therapeutic or prophylactic properties *vis-à-vis* scurvy or any other disease. Absent a record that classification under HTSUS heading 3004 is compelled by a preponderance of evidence adduced

thereon, this court concurs that the HTSUS "basket provision", subheading 1704.90.35, is where the **HALLS DEFENSE™** *Vitamin C Supplement Drops* must and do land. Judgment will enter accordingly.

Decided: New York, New York
June 21, 2004

/S/ Thomas J. Aquilino, Jr
Judge