CANADIAN INTERNATIONAL TRADE TRIBUNAL
TRIBUNAL CANADIEN DU COMMERCE EXTÉRIEUR

Ottawa, Friday, September 25, 1998

Appeal No. AP-97-010

IN THE MATTER OF an appeal heard on December 8, 1997, under section 67 of the *Customs Act*, R.S.C. 1985, c. 1 (2nd Supp.);

AND IN THE MATTER OF decisions of the Deputy Minister of National Revenue dated January 30, 1997, with respect to a request for re-determination under subsection 63(3) of the *Customs Act*.

BETWEEN

HILARY'S DISTRIBUTION LTD. **Appellant**

AND

THE DEPUTY MINISTER OF NATIONAL REVENUE **Respondent**

DECISION OF THE TRIBUNAL

The appeal is allowed.

Charles A. Gracey
Charles A. Gracey
Presiding Member

Michel P. Granger
Michel P. Granger
Secretary

333 Laurier Avenue West
Ottawa, Ontario K1A 0G7
(613) 990-2452 Fax (613) 990-2439

333, avenue Laurier ouest
Ottawa (Ontario) K1A 0G7
(613) 990-2452 Téléc. (613) 990-2439

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UNOFFICIAL SUMMARY

Appeal No. AP-97-010

HILARY'S DISTRIBUTION LTD. **Appellant**

and

THE DEPUTY MINISTER OF NATIONAL REVENUE **Respondent**

This is an appeal under section 67 of the *Customs Act* from decisions of the Deputy Minister of National Revenue made under section 63 of the *Customs Act*. The issue in this appeal is whether Kwai standardized garlic tablets are properly classified under tariff item No. 2106.90.99 as other food preparations not elsewhere specified or included, as determined by the respondent, or should be classified under tariff item No. 3004.90.99 as other medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale, as claimed by the appellant.

HELD: The appeal is allowed. Counsel for the respondent's main argument is that, in order for the goods in issue to be considered medicaments, there must be a body of scientific evidence to support any claims of efficacy or effectiveness when the goods are used for either prophylactic or therapeutic use. While this may seem like a reasonable standard, in the Tribunal's view, there is no basis for this standard in the nomenclature, the *Explanatory Notes to the Harmonized Commodity Description and Coding System* or the *Compendium of Classification Opinions to the Harmonized Commodity Description and Coding System*. Having said this, the Tribunal believes that it is equally clear that simply declaring that a product is a medicament does not make it so. In fact, in the present case, the appellant submitted a considerable body of evidence to demonstrate that the goods were medicaments. The most weighty of the documentary evidence submitted by the appellant were several studies or summaries of studies. With respect to these documents, the Tribunal generally accepts the testimony of the expert witness regarding the deficiencies in the design of various trials, to such an extent that many of the conclusions are unreliable. At the same time, it is nearly impossible to dismiss as completely unfounded the claim that the goods are well recognized to have medicinal properties. This includes the opinions of eminent specialists in cardiovascular disease. It is accepted that their views are merely those reported in the media, but they are accorded some weight. While such remarks do not prove the efficacy of the goods, they certainly indicate that the goods are popularly regarded as having medicinal qualities.

Turning to heading No. 21.06, the first question to be addressed by the Tribunal is whether the goods may be described as "food preparations." Pursuant to a review of the *Explanatory Notes to the Harmonized Commodity Description and Coding System* to heading No. 21.06, the Tribunal states that there are at least three bases upon which one must conclude that the standardized garlic tablets cannot be included in that heading. First, they are not presented as food supplements, even though they could be described as such. Second, they contain no added vitamins. Third, perhaps the most relevant basis is that, in the closing sentence, the *Explanatory Notes to the Harmonized Commodity Description and Coding System* provide that similar preparations intended for the prevention or treatment of diseases or ailments are not only excluded but specifically designated as articles of heading No. 30.03 or 30.04.

333 Laurier Avenue West
Ottawa, Ontario K1A 0G7
(613) 990-2452 Fax (613) 990-2439

333, avenue Laurier ouest
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With regard to heading No. 30.04, in the Tribunal's view, there is sufficient evidence on the record in this case indicating that the garlic tablets are used directly or indirectly to treat or prevent cardiovascular disease. Accordingly, in the Tribunal's view, the garlic tablets in issue can be described as medicaments for the purposes of classification in heading No. 30.04.

Place of Hearing:	Ottawa, Ontario
Date of Hearing:	December 8, 1997
Date of Decision:	September 25, 1998
Tribunal Member:	Charles A. Gracey, Presiding Member
Counsel for the Tribunal:	Heather A. Grant
Clerk of the Tribunal:	Margaret Fisher
Appearances:	Michael A. Sherbo, for the appellant Jan Brongers, for the respondent

CANADIAN INTERNATIONAL TRADE TRIBUNAL
TRIBUNAL CANADIEN DU COMMERCE EXTÉRIEUR

Appeal No. AP-97-010

HILARY'S DISTRIBUTION LTD. **Appellant**

and

THE DEPUTY MINISTER OF NATIONAL REVENUE **Respondent**

TRIBUNAL: CHARLES A. GRACEY, Presiding Member

REASONS FOR DECISION

This is an appeal under section 67 of the *Customs Act*[1] (the Act), heard by one member of the Tribunal,[2] from decisions of the Deputy Minister of National Revenue made under section 63 of the Act and dated January 30, 1997.

The goods in issue are Kwai standardized garlic tablets. The issue in this appeal is whether the goods in issue are properly classified under tariff item No. 2106.90.99 of Schedule I to the *Customs Tariff*[3] as other food preparations not elsewhere specified or included, as determined by the respondent, or should be classified under tariff item No. 3004.90.99 as other medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale, as claimed by the appellant.

The relevant tariff nomenclature reads as follows:

21.06	Food preparations not elsewhere specified or included.
2106.90	-Other
2106.90.99	----Other
30.04	Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale.
3004.90	-Other
3004.90.99	----Other

Mr. Allan Ingles, a pharmacist with Hilary's Distribution Ltd., testified on behalf of the appellant. Mr. Ingles explained that the Kwai standardized garlic tablets are pharmaceutically manufactured from Chinese garlic produced under controlled growth conditions. According to Mr. Ingles, the tablets contain two active ingredients: (1) alliin, an amino acid; and (2) alliinase, an enzyme. In the presence of moisture,

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1. R.S.C. 1985, c. 1 (2nd Supp.).
2. Section 3.2 of the *Canadian International Trade Tribunal Regulations*, added by SOR/95-27, December 22, 1994, *Canada Gazette* Part II, Vol. 129, No. 1 at 96, provides, in part, that the Chairman of the Tribunal may, taking into account the complexity and precedential nature of the matter at issue, determine that one member constitutes a quorum of the Tribunal for the purposes of hearing, determining and dealing with any appeal made to the Tribunal pursuant to the Act.
3. R.S.C. 1985, c. 41 (3rd Supp.).

these two ingredients interact to produce a third ingredient, namely, allicin, which gets "into the body and produces medicinal effects.[4]" Each tablet is standardized to 100 mg of garlic powder, and the daily dosage indicated on the packaging is 2 tablets, 3 times daily.

Mr. Ingles described the process by which the garlic cloves are dried and the procedures involved in producing the standardized tablets. Commenting on the recommendation that the tablets should be ingested without chewing, Mr. Ingles explained that the primary purpose for this direction was to ensure that the tablets reach the small intestine before their coating disintegrated. In cross-examination, Mr. Ingles indicated that the second purpose for this direction was to prevent the odour problem associated with the ingestion of garlic.

With reference to several documents, Mr. Ingles described the goods in issue as "a plant-derived medicine based on garlic[5]" and testified that the tablets have a positive effect on increased blood lipids and blood fluidity and were used in the treatment of arthrosclerosis (arterial calcification or hardening of the arteries). Mr. Ingles also commented on several of the documents submitted which contained references to the claim that the goods in issue are effective in preventing or treating cardiovascular disease. According to Mr. Ingles, this claim is based on eight "phenomena":

- reduction of total cholesterol
- reduction of low-density lipoprotein
- elevation of high-density lipoprotein
- anti-aggregation of blood platelets
- reduction of triglycerides
- reduction of blood sugar levels
- reduction of loss of vascular elasticity (arteriosclerosis)
- reduction in the incidence of intermittent claudication[6]

Mr. Ingles further testified that it was as a result of the effects of garlic that Lichtwer Pharma GmbH, Germany's second largest pharmaceutical company, developed the Kwai standardized garlic tablets. Furthermore, the efficacy of garlic medicines was confirmed by the Federal Health Office in Germany, and, in 1988, the "*Bundesanzeiger*" (the Federal Bulletin in Germany) published a monograph establishing that garlic is effective against increased blood lipids and in the prevention of age-dependent vascular changes.[7]

Mr. Ingles testified to the contents of a variety of fact sheets, research reports, press articles, scientific abstracts and symposia summaries, all of which dealt with the reputed beneficial effects of garlic powder tablets on the cardiovascular system. In one exhibit,[8] a clipping from the mainstream press, Dr. Kenneth Melvin, at the time a consultant cardiologist at the Women's College Hospital and Chief of Cardiology at the Doctors Hospital, was quoted as stating that "[l]arge-scale clinical trial results, involving thousands of patients from Europe and the United States, indicate clear beneficial effects in managing high

4. *Transcript of Public Hearing*, December 8, 1997, at 15.
5. *Kwai Scientific Brochure* at 4, Exhibit 11C.
6. Mr. Ingles testified that "claudication" is a description of the disease that affects people as they age and that causes pain in their legs when they walk.
7. *Supra* note 5 at 8.
8. *Women's Health Matters*, Vol. 1, No. 7, March 1995, Exhibit 11K.

blood pressure, high cholesterol and peripheral vascular disease" and that "[w]hen garlic powder tablets are taken at an average dose of 1,200 mg daily for an extended time, blood pressure is reduced modestly and cholesterol levels fall by about 12 per cent."

Mr. Ingles also cited remarks made by Dr. Gustav G. Belz, a professor of cardiology at the University of Hamburg, Germany. Dr. Belz was asked if garlic tablets could replace commonly used synthetic drugs used in cardiology, to which he replied as follows: "We could certainly state that, in a prevention mode, standardized garlic tablets are effective and that they represent a much lower risk of side effects than synthetic drugs. In a therapeutic mode, it is more delicate and we would probably need some more studies, but I myself, do not hesitate to use garlic with my patients.[9]"

Further testimony was received from Mr. Ingles concerning a scientific study entitled *Treatment of Hyperlipidaemia with Garlic-powder Tablets: Evidence from the German Association of General Practitioners' multicentric placebo-controlled double-blind study*.[10] The study concluded that standardized garlic tablets, "at a sufficiently high dosage, can be considered as an alternative for general practitioners in the treatment of mild and medium forms of hyperlipidaemia.[11]" Mr. Ingles indicated that hyperlipidaemia is a condition characterized by elevated levels of fats in the blood and is considered both a medical condition and a precursor to serious heart disease.

Mr. Ingles also testified that the appellant has a list of over 4,000 doctors in Ontario that either prescribe or recommend Kwai standardized garlic tablets to their patients on a regular basis. According to Mr. Ingles, the goods in issue are used in "adjunct" therapy, explaining that such therapy is in addition to primary therapy.[12] He then went on to testify about the prophylactic uses of standardized garlic tablets.

In cross-examination, Mr. Ingles acknowledged that the packaging for the goods in issue has no indications as to their purported use in the treatment of any disease or illness, but explained that this is in compliance with Canada's food and drug regulations, which prohibit the advertising of any drug which purports to change or mitigate the circumstances of several specific diseases, including heart disease. In a like manner, there are no references on the packaging for aspirin about the known benefits of the drug for cardiovascular purposes.

In response to a question from counsel for the respondent as to whether he would recommend that doctors prescribe garlic tablets to patients with heart disease, Mr. Ingles testified that he would so recommend to doctors, but that it was doctors who should prescribe them based on the needs of each individual case.

As to whether the eight phenomena described earlier were recognized by Mr. Ingles as diseases in and of themselves, he explained that each phenomenon was either a disease or symptomatic of a disease. In an advanced stage, some of the symptoms would be considered diseases. As an illustration, Mr. Ingles stated that an extreme loss of vascular elasticity would be described as arteriosclerosis, which is considered to be a disease. Mr. Ingles further acknowledged that factors such as age, gender, diet, pregnancy, menopause and lifestyle factors, such as smoking and fitness, have or may have an effect on one or several of the phenomena.

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9. *Natural Health Products Report,* August/September 1997 at 14, Exhibit 11L.
10. Study Group on Phytotherapy of the German Association of General Practitioners, Exhibit 11X.
11. *Ibid.* at 7.
12. On this issue, reference was made to a study by Dr. Melvin entitled *Effects of Garlic Powder Tablets on Patients with Hyperlipidaemia in Canadian Clinical Practice,* Exhibit 11W.

Mr. Ingles explained, however, that the trials were designed to take into account such factors by, for example, balancing the gender or the age distribution in the control and experimental groups.

With respect to the documentary evidence on the record supplied by the appellant, Mr. Ingles acknowledged that not all of the documents represented actual studies, rather many were reports of studies. Mr. Ingles also stated that it was well understood and generally accepted, based on a well-known study referred to as the Framingham Study, that a 1 percent reduction in cholesterol is equal to a 2 percent reduction in the risk associated with cardiovascular disease. Mr. Ingles acknowledged that this particular study was not on the record, but that it was well known in the medical community. Based on the finding of that study, Mr. Ingles testified that a 12 percent reduction in cholesterol, which is the median reduction that the Kwai standardized garlic tablets purport to achieve, represents roughly a 25 percent reduction in the risk associated with heart disease.

Counsel for the respondent questioned the validity of the conclusions in some of the studies because of either an inadequate explanation of or a deficiency in the studies' experimental design. For example, counsel pointed out that several studies contained both men and women of various ages and that it was not apparent that these factors had been properly taken into account in the design of the study. Mr. Ingles responded to this suggestion by stating that there had been attempts to balance factors such as age and gender, but that what was relevant was the statistical significance of the results.

In response to counsel for the respondent's suggestion that the guarded conclusions reported in many of the trials were an admission that the efficacy of garlic is somewhat suspect, Mr. Ingles suggested that such a conclusion would be akin to questioning the efficacy of aspirin for the treatment of a normal headache just because it was not as potent as morphine. He indicated that there were degrees of heart disease and suggested that garlic therapy is beneficial, even though it is not as potent as some other treatments.

Dr. Sam Kacew, Department of Pharmacology at the University of Ottawa, testified as an expert witness on behalf of the respondent in the field of pharmacology. Dr. Kacew was also given permission to give opinion evidence as to whether the documents put into evidence by the appellant constituted reliable scientific evidence that the goods in issue are medicaments.

In general, Dr. Kacew testified that the reports submitted by the appellant were not reliable evidence that garlic was a medicament because the reports contained no data and cited no scientific evidence. This deficiency was repeatedly pointed out by Dr. Kacew in response to questions regarding the value of the reports. Dr. Kacew testified in considerable detail as to the methodological flaws and statistical deficiencies inherent in the experimental design of many of the studies. These deficiencies can be summarized as the failure to properly partition or otherwise account for most of the variables in the program design. According to Dr. Kacew, the result of these deficiencies is that it is not possible to determine if the observed effect was the result of the treatment or whether it was caused by one of the variables. As an example, Dr. Kacew stated that, if men and women are involved in a trial, they may have different blood lipid levels because of their gender. As such, they must be separated in the trial in order for the study to have meaningful results.

Dr. Kacew also pointed out that several of the documents were not studies, but merely reports of med-line searches. In two or three cases, he acknowledged that the documents before the Tribunal were actual studies, but that, in each of these cases, the design of the trial was flawed and that the conclusions reached and reported could not be considered reliable.

The appellant's representative argued that proof of product efficacy is not a requirement for classifying goods in heading No. 30.04, but that classification is based on concepts of intended use and the goods having been put up in measured doses for retail sale. He submitted that counsel for the respondent has produced no Legal or Section Notes to support his contention that proof of efficacy is required. In support of the appellant's position, the representative cited Note 2 to Section VI of Schedule I to the *Customs Tariff*, which states that "goods classifiable in heading No. 30.04 … by reason of being put up in measured doses or for retail sale are to be classified in [that heading] and in no other heading of the Nomenclature."

With reference to the Tribunal's decision in *Hung Gay Enterprises Ltd.* v. *The Deputy Minister of National Revenue*,[13] in which the product was described as a traditional Chinese herbal remedy prescribed to cure "a disharmony of the 'yin' and the 'yang,'[14]" the appellant's representative pointed out that the Tribunal had found the product to be a medicament, in spite of a lack of evidence regarding the efficacy of the product, on the basis that the product was put up for retail sale and contained a measuring glass and instructions on dosage.

The appellant's representative further noted the Tribunal's decision in *Yves Ponroy Canada* v. *The Deputy Minister of National Revenue*,[15] in which the Tribunal determined that food supplements which had an indication as to use for the prevention or treatment of any disease or ailment may be classified in heading No. 30.04, provided they are put up in measured doses or in forms or packings for retail sale.

In the view of the appellant's representative, if proof of efficacy were required as a condition of classification in heading No. 30.04, the proper classification of similar products would require a high degree of expertise to evaluate the supporting research and, moreover, every "medicament" case would require a decision from the Tribunal.

In addressing the relevance of the Tribunal's decision in *Flora Distributors Ltd.* v. *The Deputy Minister of National Revenue*,[16] the appellant's representative noted that the issue in that appeal was whether the garlic capsules were essential oils classifiable in heading No. 33.01 or food supplements classifiable in heading No. 21.06. In deciding that the garlic capsules were not essential oils but food supplements, the representative pointed out that the proposition that the goods might actually be medicaments was never advanced nor was any evidence to that effect put before the Tribunal in that appeal.

The appellant's representative then drew the Tribunal's attention to paragraph 16 of the *Explanatory Notes to the Harmonized Commodity Description and Coding System*[17] (the Explanatory Notes) to heading No. 21.06, which states, in part, as follows:

> Preparations, often referred to as *food supplements*,… put up in packagings with indications that they maintain general health or well-being. Similar preparations, however, intended for the prevention or treatment of diseases or ailments are **excluded** (**heading 30.03** or **30.04**).

The appellant's representative next made reference to Note A(12) of the Explanatory Notes to heading No. 13.02 to show that, at another place in the tariff nomenclature, garlic was included under a

13. Appeal No. AP-96-044, June 5, 1997.
14. *Ibid*. at 5.
15. Appeal No. AP-96-117, December 5, 1997.
16. Appeal No. AP-94-199, October 8, 1996.
17. Customs Co-operation Council, 1st ed., Brussels, 1986.

grouping of "[o]ther medicinal extracts." Furthermore, the Tribunal's decision in *UpJohn Inter-American Corporation* v. *The Deputy Minister of National Revenue for Customs and Excise*,[18] to which counsel for the respondent referred, was of little assistance in this appeal, since it dealt with heading No. 30.03 and not heading No. 30.04.

With respect to heading No. 21.06, the appellant's representative argued that, inasmuch as that heading referred to "Food preparations not elsewhere specified," this is a residual classification to be used as a last resort. He submitted that, if there were another suitable heading, it would apply. The representative also relied on the decision of the Federal Court of Canada - Trial Division in *Shaklee Canada Inc.* v. *Her Majesty the Queen*[19] to argue that the goods in issue were neither food nor food preparations.

The appellant's representative took note of the seven opinions extracted from the *Compendium of Classification Opinions to the Harmonized Commodity Description and Coding System*[20] (the Classification Opinions) by the respondent and pointed out that only three of the seven identified heading No. 21.06. Therefore, there were only three of any possible assistance. In respect of these three, he pointed out that these opinions were arrived at in committee without the benefit of expert testimony. Moreover, none of the opinions dealt with the goods in issue or provided reasons as to how the committee arrived at its decision to classify certain goods in heading No. 21.06.

In conclusion, the appellant's representative submitted that the goods in issue should be classified in heading No. 30.04 on the basis that they are proven to be therapeutic or prophylactic and put up for retail sale and that their intended use is to lower cholesterol. However, he did concede that there is no indication on the package of intended use, but explained that such indications were absent in compliance with domestic regulations. In any event, such indications were apparent in brochures and in scientific literature.

Counsel for the respondent began his argument by typifying this case and similar ones as "the health food issue." He stated that the issue surrounds the classification of edible products whose consumption is purported to be of some benefit to human health. Specifically, should these goods be classified as food preparations in heading No. 21.06 or as medicaments in heading No. 30.04? Counsel argued that, until the issuance of the Tribunal's decision in *Yves Ponroy*, the respondent has assumed that the issue was essentially a factual one and that, if an importer could provide evidence to substantiate a claim that a health food product or herbal medicine does indeed prevent or treat disease, the goods would be classified as medicaments. However, if the evidence merely shows that the products contribute to general well-being, as opposed to being truly effective in combating disease, then the products would be classified as food preparations.

However, with the Tribunal's decision in *Yves Ponroy*, counsel for the respondent submitted that the Tribunal appears to have ruled that an importer has no obligation to show that a product is scientifically proven to be an effective medicament in order to be classified in heading No. 30.04, but that, if the product is marked with an indication that it is to be used in the treatment or prevention of disease and put up in measured doses or in forms or packings for retail sale, it qualifies as a medicament.

In the view of counsel for the respondent, the Tribunal applied the wrong test in *Yves Ponroy*. He requested the Tribunal to rule instead that medical efficacy is relevant to a determination of whether imported goods are medicaments, as opposed to food preparations. As such, counsel submitted that this appeal should

18. Appeal No. AP-90-197, January 20, 1992.
19. Unreported, Court File No. T-3012-90, February 28, 1995.
20. Customs Co-operation Council, 1st ed., Brussels, 1987.

be dismissed for lack of evidence. In the alternative, counsel submitted that, since the goods in issue have no indications for use in the prevention or treatment of disease, they would not even qualify as "medicaments" based on the standard applied in *Yves Ponroy*.

Counsel for the respondent submitted that it is well established that the onus in an appeal rests with the appellant to show that the respondent's determination was incorrect. He also submitted that, contrary to the assertions of the appellant's representative, Classification Opinions are generally relevant to the determination of classification matters pursuant to section 11 of the *Customs Tariff*.

Continuing with his argument, counsel for the respondent submitted that the goods in issue are merely crushed garlic encased in a coating and that garlic is clearly a food. He drew attention to a definition of "garlic" found in *The Concise Oxford Dictionary of Current English*,[21] which reads, in part, as follows: "any of various alliaceous plants … the strong-smelling pungent-tasting bulb of this plant, used as a flavouring in cookery.[22]" Citing this definition, counsel submitted that the only difference between ordinary garlic and the goods in issue is the fact that they have been prepared and processed, so as to be encased in a multi-layer coating in order to permit the consumer to ingest the garlic in an odour-free manner. Counsel further submitted that the goods in issue are "food preparations" and noted that the word "preparation" is defined as a "specially prepared substance, esp. a food or medicine.[23]"

Counsel for the respondent also referred to the Tribunal's decision in *Flora Distributors* in further support. Although the facts in that case were not directly in point, the Tribunal observed the following in its decision:

> In the Tribunal's view, the goods in issue do meet the general description of food preparations not elsewhere specified or included in heading No. 21.06, as well as in the related explanatory notes. The Explanatory Notes to heading No. 21.06 provide that it includes "[p]reparations, often referred to as *food supplements*, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing added vitamins and sometimes minute quantities of iron compounds." The Explanatory Notes further provide that the "preparations are often put up in packagings with indications that they maintain general health or well-being." The evidence before the Tribunal indicates that the goods in issue are food supplements, based on extracts from plants, in this case garlic cloves, put up in packagings.[24]

Counsel for the respondent contended that the present case depicts the same situation. He particularly noted that the Explanatory Notes to heading No. 21.06 refer to, among other things: "Preparations for use, either directly or after processing … for human consumption.… (8) Edible tablets with a basis of natural or artificial perfumes … (14) Products consisting of a mixture of plants or parts of plants ... of different species or consisting of plants or parts of plants … of a single or of different species mixed with other substances ... which are not consumed as such, but which are of a kind used for making herbal infusions or herbal 'teas', including products which are claimed to offer relief from ailments or contribute to general health and well-being…. (15) Mixtures of plants … not consumed as such, but of a kind used either directly for flavouring beverages." While counsel conceded that the goods in issue do not fall squarely under any of these paragraphs, he submitted that the Explanatory Notes are prefaced by the words "*inter alia*,"

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21. Eighth ed. (Oxford: Clarendon Press, 1990).
22. *Ibid*. at 486.
23. *Ibid.* at 941.
24. *Supra* note 16 at 7.

thereby indicating that the list of goods in the Explanatory Notes is not exhaustive of those classifiable in heading No. 21.06.

In arguing that the goods in issue are not medicaments, counsel for the respondent submitted that the Explanatory Notes to heading No. 30.03, specifically the reference to "[m]ixed medicinal preparations such as those listed in an official pharmacopoeia, proprietary medicines, etc.," apply equally to heading No. 30.04 because the two headings are so clearly related. The only real distinction between the two headings is that heading No. 30.03 covers bulk products, while heading No. 30.04 applies to products put up in packings for retail sale.

Turning to the jurisprudence, counsel for the respondent submitted that the appellant is obliged to demonstrate that the goods are medicinal preparations that are used to treat or prevent disease.[25] He argued that mere indications that the goods are so used is insufficient. There must be actual scientific evidence of efficacy provided. He argued that this position is supported by the Explanatory Notes to heading No. 30.04, which state, in part, that goods that are claimed to offer relief from ailments or to contribute to general health and well-being, but whose infusions do not constitute a therapeutic or prophylactic dose of an active ingredient specific to a particular ailment, are excluded from this heading. He proposed that the Explanatory Notes invite the Tribunal to make a distinction between health products which merely claim to offer relief from ailments and true medicaments which contain a therapeutic or prophylactic dose of an active ingredient. In other words, a food preparation is a product that merely claims to offer relief, while a medicament is a product which, in fact, offers relief.

Counsel for the respondent then argued that several of the Classification Opinions contain numerous examples of products which claim medicinal properties, but which are not included in heading No. 30.04. He noted, for example, that the Nomenclature Committee that issues the Classification Opinions decided that ginseng root was not a medicament. It was noted in the Classification Opinion concerning ginseng that the "therapeutic or prophylactic effects of ginseng were rather doubtful and ginseng was not generally accepted as a medicament." He argued, based on those rulings, that what the committee had in mind was that some scientific evidence must be provided to demonstrate that the goods are effective. He noted that, in its decision in *Yves Ponroy*, the Tribunal did not explicitly consider the views and rulings of the Nomenclature Committee. While counsel acknowledged that the Explanatory Notes do not explicitly state that scientific proof is required, he doubted that any Explanatory Notes set out the exact form of evidence that is required.

Counsel for the respondent submitted that scientific evidence is required in all cases, with the possible exception of certain medicaments whose efficacy is so generally accepted and notorious that judicial notice could effectively be taken of the fact that they are medicaments.

In arguing that the appellant has failed to prove its claim that the goods in issue are medicaments, counsel for the respondent focused primarily on the alleged effects of garlic on cholesterol and triglyceride levels. He argued that none of the documents submitted into evidence by the appellant sustains these claims. With the assistance of the witness for the respondent, the studies or trials were shown to be unreliable, and the conclusions drawn by the appellant regarding the therapeutic or prophylactic uses of the goods were unsubstantiated.

Counsel for the respondent also noted that, even if the *Yves Ponroy* "test" were to be applied in this case, the goods in issue would fail the test, as they have no indication on their packaging regarding any

25. *Supra* note 18.

alleged therapeutic or prophylactic use. While he acknowledged the witness for the appellant's explanation for the absence of any such indication, counsel submitted that such restrictions are irrelevant.

In conclusion, counsel for the respondent submitted that, even if the appellant were correct in its view that the Explanatory Notes to heading No. 30.03 cannot be applied to heading No. 30.04, this logic would apply equally to the appellant's argument that the Explanatory Notes to heading No. 13.02 support its claim that garlic extracts are medicaments. Moreover, the relevance of efficacy was made apparent by the Customs Co-operation Council.

In classifying goods in Schedule I to the *Customs Tariff*, the Tribunal is cognizant that Rule 1 of the *General Rules for* the *Interpretation of the Harmonized System*[26] is of the utmost importance. This rule states that classification is first determined according to the terms of the headings and any relative Chapter Notes. Therefore, the Tribunal must determine whether the goods in issue are named or generically described in a particular heading. If they are, then they must be classified therein subject to any relative Chapter Note. Section 11 of the *Customs Tariff* provides that, in interpreting the headings or subheadings, the Tribunal shall have regard to the Classification Opinions and the Explanatory Notes.

The Tribunal agrees with counsel for the respondent that the present case is essentially one in a series that address the classification of goods that might, on the one hand, be considered other food preparations or, on the other hand, medicaments. The Tribunal also notes that many of the Explanatory Notes that must be considered are not themselves perfectly clear and unambiguous and that it is sometimes difficult to discover the true intent of a number of statements.

That the goods in issue can potentially be classified in either heading No. 21.06 or heading No. 30.04 appears apparent. Clearly, garlic is a food. However, what is not so apparent is whether standardized garlic powder encased in a coating and presented for retail sale in tablet form should be regarded as a food. By contrast, it is equally apparent that the garlic tablets are being represented, in general, as medicaments and are so regarded by many.

Counsel for the respondent's main argument is that, in order for the goods in issue to be considered medicaments, there must be a body of scientific evidence to support any claims of efficacy or effectiveness when the goods are used for either prophylactic or therapeutic use. While this may seem like a reasonable standard, in the Tribunal's view, there is no basis for this standard in the nomenclature, the Explanatory Notes or the Classification Opinions.

The appellant's representative contends that the Explanatory Notes make it quite clear that the packaging and the method of presentation are determinative of whether the goods in issue fall within one heading or another. Nonetheless, having taken this position, the representative has introduced a large number of documents to support his claim that the goods are medicaments based on claims of efficacy.

For his part, counsel for the respondent readily concedes that, in the face of compelling evidence as to efficacy, the goods would be classified as medicaments in heading No. 30.04, but that there is no proof to support any such claim.

The Tribunal believes, for its part, that there must be reasonable indications that the goods are medicaments, but does not consider it reasonable or necessary to apply the exacting standards as urged by

26. *Supra* note 3, Schedule I.

counsel for the respondent. The Tribunal can find no support in the terms of the headings or the Explanatory Notes for the proposition that documented unassailable scientific proof of efficacy is a requirement for classification. Indeed, if this were the case, the Explanatory Notes provided would be rendered redundant.

Having said this, the Tribunal believes that it is equally clear that simply declaring that a product is a medicament does not make it so. In fact, in the present case, the appellant submitted a considerable body of evidence to demonstrate that the goods were medicaments. The most weighty of the documentary evidence submitted by the appellant were several studies or summaries of studies. With respect to these documents, the Tribunal generally accepts the testimony of the expert witness regarding the deficiencies in the design of various trials, to such an extent that many of the conclusions are unreliable. At the same time, it is nearly impossible to dismiss as completely unfounded the claim that the goods are well recognized to have medicinal properties. This includes the opinions of eminent specialists in cardiovascular disease, such as Dr. Melvin and Dr. Belz. It is accepted that their views are merely those reported in the media, but they are accorded some weight. While such remarks do not prove the efficacy of the goods, they certainly indicate that the goods are popularly regarded as having medicinal qualities.

In attempting to apply the Explanatory Notes to heading No. 30.03 to heading No. 30.04, counsel for the respondent argued that the only real distinction between the goods classifiable in heading No. 30.03 and those classifiable in heading No. 30.04 was simply that the former included bulk goods, while the latter were put up in packagings for retail sale. It would seem to the Tribunal that the reason for the distinction is obvious. When goods are presented in bulk, it is necessary that they be goods known as medicaments and, hence, the reference to goods listed in official pharmacopoeia, proprietary medicines, etc. But when the goods are "put up in measured doses for retail sale," no such further information is necessary, since they meet the requirement of the Explanatory Notes.

Turning to heading No. 21.06, the first question to be addressed by the Tribunal is whether the goods may be described as "food preparations." In the Tribunal's view, the answer to this question is not obvious. The goods in issue are presented in standardized tablet form, and it is not apparent from their appearance that they are food supplements. However, reference to the Explanatory Notes to heading No. 21.06 reveals that many products that may not appear to be food preparations are, nonetheless, categorized as such.

It is instructive to read the Explanatory Notes to heading No. 21.06 in their entirety to get a full sense of their intended scope. The first part of the Explanatory Notes declares that certain "food preparations" fall in this particular heading "[p]rovided that they are not covered by any other heading of the Nomenclature." In other words, this heading is a residual heading for goods not provided elsewhere. The Explanatory Notes then describe two groups. Group A refers to "[p]reparations for use, either directly or after processing (such as cooking, dissolving or boiling in water, milk, etc.), for human consumption." Group B refers to "[p]reparations consisting wholly or partly of foodstuffs, used in the making of beverages or food preparations." The goods in issue do not fit into either of these groups, as they are not used in any aspect of food preparation. Nevertheless, the Explanatory Notes continue to offer no less than 16 examples of the type of goods included in heading No. 21.06. Of these 16 examples, the first 15 are not relevant, inasmuch as, in each case, the type of goods described are invariably used in the preparation of other foods or beverages or for consumption or are intended for ingestion directly as a food (e.g. "(5) Natural honey enriched with bees' royal jelly").

The remaining examples are "[p]reparations, often referred to as *food supplements*, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing added vitamins and sometimes minute quantities of iron compounds. These preparations are often put up in packagings with indications that they maintain general health or well-being. Similar preparations, however, intended for the prevention or treatment of diseases or ailments are **excluded** (**heading 30.03** or **30.04**)." (Emphasis added)

There are at least three bases upon which one must conclude that the standardized garlic tablets cannot be included in heading No. 21.06. First, they are not presented as food supplements, even though they could be described as such. Second, they contain no added vitamins. Third, perhaps the most relevant basis is that, in the closing sentence, the Explanatory Notes provide that similar preparations *intended* for the prevention or treatment of diseases or ailments are not only excluded but specifically designated as articles of heading No. 30.03 or 30.04.

It is noted here that the sentence uses the word "intended," which is a far lower standard than that urged by the respondent.

One could stop here with the analysis, inasmuch as it is apparent that there is no obvious accommodation for the goods in issue anywhere in heading No. 21.06 and that none of the 16 examples can be reasonably interpreted to include the goods. However, it is noted that the 16 examples are prefaced by "*inter alia*," meaning that the list is not exhaustive. Thus, it is prudent to examine the Explanatory Notes relating to heading No. 30.04 to determine if they clearly include or specifically exclude the goods in issue.

With regard to heading No. 30.04, the Tribunal notes that this heading provides for the classification of "[m]edicaments … consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale."

While counsel for the respondent has urged the Tribunal to reconsider its reasoning in *Yves Ponroy*, specifically with regard to the issue of the efficacy of goods classifiable in heading No. 30.04, the Tribunal sees no reason to do so, for the reasons outlined earlier. In the Tribunal's view, the Explanatory Notes to heading No. 30.04 do not require that the efficacy of products classifiable in that heading be scientifically proven. In other words, it is not necessary to show that a product actually cures a disease or illness in order for that product to be considered a medicament.

The Tribunal notes its comments in *Baxter Corporation* v. *The Deputy Minister of National Revenue*,[27] in which the Tribunal referred to its decision in *UpJohn*, when it held that, "[w]ith regard to heading No. 30.04, the Tribunal interprets this provision as referring to substances used to treat or prevent diseases. This is indicated by the dictionary definitions … of the word 'therapeutic,' which means 'curative; of the healing art' and the word 'prophylactic,' which means 'tending to prevent disease or other misfortune.'[28]" In the Tribunal's view, this means that, in order for a product to be classified in heading No. 30.04, it must show some "curative" properties in order to be accepted as being used in the treatment of a disease. The Tribunal notes that *The New Lexicon Webster's Dictionary of the English Language* defines the word "curative" as "having remedial properties, helping to cure.[29]" In the Tribunal's view, there is sufficient evidence on the record in this case indicating that the garlic tablets have remedial properties which

27. Appeal No. AP-93-092, July 26, 1994.
28. *Ibid.* at 4.
29. (New York: Lexicon Publications, 1987) at 236.

help “cure” or “treat” cardiovascular disease. Accordingly, in the Tribunal’s view, the garlic tablets in issue can be described as medicaments for the purposes of classification in heading No. 30.04.

While the Tribunal acknowledges that, pursuant to section 11 of the *Customs Tariff*, it shall have regard to the Classification Opinions in interpreting headings and subheadings, in its view, none of the Classification Opinions submitted by counsel for the respondent is relevant to determining the classification of the goods in issue. The Classification Opinions submitted by counsel were in respect of products other than garlic capsules. Moreover, the Classification Opinions did not address the issue of efficacy in a meaningful way.

Since all the conditions of heading No. 30.04 have, in the Tribunal’s view, been met, the Tribunal finds that the goods in issue should be classified under tariff item No. 3004.90.99.

Accordingly, the appeal is allowed.

Charles A. Gracey
Charles A. Gracey
Presiding Member