CANADIAN INTERNATIONAL TRADE TRIBUNAL
TRIBUNAL CANADIEN DU COMMERCE EXTÉRIEUR

Ottawa, Friday, July 24, 1998

**Appeal No. AP-97-002**

IN THE MATTER OF an appeal heard on October 6, 1997, under section 67 of the *Customs Act*, R.S.C. 1985, c. 1 (2nd Supp.);

AND IN THE MATTER OF a decision of the Deputy Minister of National Revenue dated January 28, 1997, with respect to a request for re-determination under section 63 of the *Customs Act*.

**BETWEEN**

**FLORA MANUFACTURING & DISTRIBUTING LTD.** **Appellant**

**AND**

**THE DEPUTY MINISTER OF NATIONAL REVENUE** **Respondent**

**DECISION OF THE TRIBUNAL**

The appeal is allowed.

Raynald Guay
Raynald Guay
Presiding Member

Patricia M. Close
Patricia M. Close
Member

Arthur B. Trudeau
Arthur B. Trudeau
Member

Michel P. Granger
Michel P. Granger
Secretary

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# UNOFFICIAL SUMMARY

## Appeal No. AP-97-002

**FLORA MANUFACTURING & DISTRIBUTING LTD.** **Appellant**

**and**

**THE DEPUTY MINISTER OF NATIONAL REVENUE** **Respondent**

This is an appeal under section 67 of the *Customs Act* from a decision of the Deputy Minister of National Revenue. The issue in this appeal is whether devil's claw 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 consisting of mixed or unmixed products for therapeutic or prophylactic uses, as claimed by the appellant.

**HELD:** The appeal is allowed. In the Tribunal's view, the goods in issue are not included in the common understanding given to the term "food preparations." As a result, they cannot be classified under tariff item No. 2106.90.99. The Tribunal accepts the evidence of the appellant's witnesses that devil's claw is used in the treatment of arthritis, which is a disease or an illness. The Tribunal attributes particular weight to the testimony of a pharmacist with many years of experience in dealing with patients who have used the goods in issue, who explained that the ingredients in devil's claw act as an anti-inflammatory and reduce pain, stiffness and swelling caused by arthritis. The Tribunal is, therefore, of the view that the goods in issue can be described as a medicament. Furthermore, there is no requirement in the relative Chapter Notes, the *Explanatory Notes to the Harmonized Commodity Description and Coding System* or the terms of the heading that a product must be scientifically proven to be an effective medicament in order to be classified in heading No. 30.04. In other words, it does not need to be shown that a product actually cures a disease or illness. However, in the Tribunal's view, there must be some "curative" properties shown in order for a product to be accepted as being used in the treatment of a disease and for it to be classified in heading No. 30.04. The Tribunal finds that the appellant has met that burden in the present case.

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|---|---|
| Place of Hearing: | Vancouver, British Columbia |
| Date of Hearing: | October 6, 1997 |
| Date of Decision: | July 24, 1998 |
| Tribunal Members: | Raynald Guay, Presiding Member<br>Patricia M. Close, Member<br>Arthur B. Trudeau, Member |
| Counsel for the Tribunal: | Joël J. Robichaud |
| Clerk of the Tribunal: | Anne Jamieson |
| Appearances: | Michael Sherbo, for the appellant<br>Edward (Ted) Livingstone, for the respondent |

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**Appeal No. AP-97-002**

**FLORA MANUFACTURING & DISTRIBUTING LTD.** **Appellant**

**and**

**THE DEPUTY MINISTER OF NATIONAL REVENUE** **Respondent**

TRIBUNAL: RAYNALD GUAY, Presiding Member
PATRICIA M. CLOSE, Member
ARTHUR B. TRUDEAU, Member

## REASONS FOR DECISION

This is an appeal under section 67 of the *Customs Act*[1] (the Act) from a decision of the Deputy Minister of National Revenue dated January 28, 1997, made pursuant to section 63 of the Act.

The goods in issue, called Pagosid, are described as devil's claw root tablets. They are manufactured from an extract of the secondary tubers of devil's claw. They are composed of a mixture of a plant extract, lactose, maltose and possibly other ingredients. The goods in issue are sold in various forms in health food stores and pharmacies that sell traditional medicines.

At the time of importation, the goods in issue were classified under tariff item No. 3004.90.99 of Schedule I to the *Customs Tariff*[2] as other medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses. Pursuant to paragraph 61(*b*) of the Act, the respondent issued a detailed adjustment statement and re-classified the goods in issue under tariff item No. 2106.90.99 as other food preparations not elsewhere specified or included. Pursuant to paragraph 63(1)(*a*) of the Act, the appellant filed a request for re-determination of the tariff classification under tariff item No. 3004.90.99. The respondent denied the request.

The issue in this appeal is whether the goods in issue are properly classified under tariff item No. 2106.90.99, as determined by the respondent, or should be classified under tariff item No. 3004.90.99, as claimed by the appellant. For purposes of this appeal, the relevant tariff nomenclature reads as follows:

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|---|---|
| 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 |

1. R.S.C. 1985, c. 1 (2nd Supp.).
2. R.S.C. 1985, c. 41 (3rd Supp.).

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The appellant's first witness was Mr. Bruce Dales, Biochemist, Research & Development, for Flora Manufacturing & Distributing Ltd. The Tribunal denied the request of the appellant's representative that Mr. Dales be qualified as an expert witness. In the Tribunal's view, he did not possess the qualifications usually attributed to such a witness. He, therefore, testified as an ordinary witness. He identified the goods in issue and described them as a traditional herb used originally in South Africa, but now used and sold worldwide to treat the symptoms of arthritis. Mr. Dales then referred to several documents which were introduced into evidence to support the appellant's claim that the goods in issue are medicaments rather than food preparations. He testified that most of these documents are used by the Department of Health to prepare its drug status manual and by companies, such as the appellant, to obtain drug identification numbers (DINs).

The first document to which Mr. Dales referred suggested that devil's claw is used in "supportive therapy for degenerative disorders of the locomotor system.[3]" Another document suggested that "the drug has antirheumatic and antiphlogistic properties, corresponding to those of pyrazolone derivatives.[4]" The third document stated that "German clinical studies suggest that the plant does have antiinflammatory properties comparable to antiarthritic phenylbutazine.[5]" Mr. Dales referred to a fourth document which, he explained, provides lists and summaries of a number of studies and the pharmacological effects of devil's claw. The next document to which he referred was the *British Herbal Compendium*,[6] used by licensed herbalists practising medicine in England. He noted that, under the heading "Indications," this document states: "Painful arthroses, tendinitis; dyspepsia, lack of appetite.[7]" Next, Mr. Dales referred to a series of three articles consisting of studies done in the People's Republic of China that proved that the goods in issue are used in relieving the symptoms of arthritis, i.e. pain and inflammation.[8] He also referred to a study which mentioned a number of cardiovascular types of effects that devil's claw has on dogs.[9]

Next, Mr. Dales referred to an article written in German. He explained that what was said in the document is that the glycoside in the devil's claw is not very effective, but that the devil's claw extract as a whole is very effective in relieving pain and inflammation caused by arthritis. Mr. Dales referred to a number of other studies on the effectiveness of devil's claw, four of which were from the *Journal of Ethnopharmacology*. He explained that these studies explain the in vitro and clinical effects of devil's claw root. More specifically, the first one discusses the effects of devil's claw on isolated muscle preparations; the second, the effects of devil's claw on cardiovascular activity; the third, the scanning electron microscope observations in locating the active chemicals; and the fourth, the effects of devil's claw on the heart. Next, a document[10] was introduced into evidence which provided the nutrition facts about the goods in issue.

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3. *Herbal Drugs and Phytopharmaceuticals, A handbook for practice on a scientific basis* (Stuttgart: Medpharm Scientific, 1994) at 249.
4. R.F. Weiss, *Herbal Medicine* (Beaconsfield: Beaconsfield) at 266.
5. J.A. Duke, *CRC Handbook of Medicinal Herbs* (Boca Raton: CRC Press) at 222.
6. Vol. 1, British Herbal Medicine Association.
7. *Ibid*. at 78.
8. Y. Peida and Y. Xuyan, *Preliminary Clinical Observation On Treatment of 40 cases of Arthritis with Pagosid*, Branch of Rheumatology and Clinical Immunology, Department of Internal Medicine, First Affiliated Hospital, Sun Yet Sen University of Medical Science.
9. F. Occhiuto and A. De Pasquale, *Electrophysiological and Haemodynamic Effects of Some Active Principles of Harpagophytum Procubens DC. in the Dog*, Department of Pharmaco-Biological, University of Messina, 1990.
10. Exhibit A-4.

Mr. Dales said that, according to this document, the goods in issue have no nutritional value. More specifically, three tablets contain 2 percent of vitamin C. Many tablets would, therefore, have to be taken to get a healthy amount of vitamin C. Mr. Dales explained that the document provides that this would cause a number of gastrointestinal complications.

In cross-examination, Mr. Dales testified that he is not a nutritionist. He also testified that all of the studies to which he referred in his examination in chief were paid for by Dr. Dünner, the manufacturer of the goods in issue. He explained that a statistically insignificant result does not necessarily mean a negative result. He said that "statistically significant" means 95 percent. If the people who conducted the studies found that there was a 70 percent chance of devil's claw being effective, they would say that it is not effective. They need a result of at least 95 percent. Mr. Dales testified that none of the papers to which he referred stated that devil's claw is effective in treating arthritis. Rather, the authors of the papers are attempting to describe the active ingredients of the drug.

Counsel for the respondent then asked Mr. Dales to read from three documents[11] introduced into evidence. He read a passage from the first document entitled "Investigations of *Harpagophytum procumbens* (Devil's Claw) in the treatment of experimental inflammation and arthritis in the rat," which provided that: "If these tests can be regarded as predictive of efficacy in humans, Devil's Claw when used at the recommended dose would not be expected to show anti-arthritic activity." A passage from a second document entitled "Devil's claw (*Harpagophytum procumbens*): pharmacological and clinical studies," from which he read, stated that: "The purpose of these studies was to determine whether a prima facie case could be made for undertaking further studies in patients, including controlled studies." It also provided that: "The results described provide little justification for such action, and the usefulness of devil's claw as an anti-rheumatic agent remains unproved." The final document entitled "Devil's Claw (*Harpagophytum procumbens*): no evidence for anti-inflammatory activity in the treatment of arthritic disease," from which Mr. Dales read, provided as follows: "The lack of pharmacologic activity observed in these studies of efficacy, together with the fact that Grahame and Robinson could not demonstrate any significant change in 12 arthritic patients in a preliminary 6-week clinical trial, raises questions as to the rationale for the use of Devil's Claw in the treatment of arthritic disease."

Mr. Dales was asked to read the list of ingredients contained in each tablet of the goods in issue. They included the following: "Powered extract of: Devil's Claw root (*Harpagophytum procumbens*) 1:2 .. 410 mg (equivalent to 820 mg Devil's Claw root)." Mr. Dales was also asked to read the suggested use on the bottle. It provided the following: "Take 1 tablet three times daily before meals. A course of tablets should be taken for at least four weeks and can be extended to eight weeks or more. Store in a cool, dry place."

In answering questions from the Tribunal, Mr. Dales testified that the goods in issue do not have a DIN. He explained that a DIN is not required in order to sell medicine in Canada. He said that, in order to obtain a DIN, a request must be made to the Department of Health (Health Canada). According to Mr. Dales, most traditional medicines, which are being sold and used in Canada today, do not have DINs. He explained that, in general, manufacturers do not like to get DINs because there is a lot of red tape involved, it does not affect the quality of the product if they get one, and people would take the drug regardless of whether or not it has a DIN. Mr. Dales testified that there is no real advantage of having a DIN. He went through the studies presented into evidence and said that they date back as far as the 1970s, while some are as recent as 1997. He noted that the appellant's studies are more recent than those of the

11. Exhibit B-1.

respondent. Mr. Dales explained that "pharmacopoeias" are documents which are published in countries that use traditional medicines. They act as references for those who use or prescribe herbal medicines. They explain how these drugs must be used in order to be safe and efficacious. He said that the "pharmacopoeias" are used worldwide.

Mr. Dales testified that the goods in issue have been on the market for hundreds of years. He said that, at first, devil's claw was used to treat ulcers, before being used as an anti-inflammatory and as an analgesic. He explained that "pharmacologic activity" means the activity of the "herb" in general. He said that, if an herb is meant to be good for arthritis, for example, then its pharmacologic activity is for arthritis. He testified that the primary use of devil's claw is as an anti-inflammatory and a painkiller. However, he said that, just like aspirin, it can also relieve fevers. He testified that nowhere in the world is this product being sold as a food product and that someone using it as such would suffer many side effects. Furthermore, it would be very expensive. There are no food standards for devil's claw because it has never been taken as a food.

In answering counsel for the respondent, who followed up on questions from the Tribunal, Mr. Dales testified that, if the appellant indicated on the package that devil's claw could be used as an analgesic or an anti-inflammatory, then Health Canada could request that it obtain a DIN for that product. He testified that, for the appellant, it would not be useful to indicate on the package what the product can be used for because this information is available where the product is being sold. Furthermore, in view of their selling price, no one is going to buy the goods in issue unless they know why they are buying them. He added that he has tasted the goods in issue and that they are pretty bad tasting. He did not agree with counsel that, if the appellant indicated on the package what devil's claw is being used for, the government would want to regulate it.

In re-examination, Mr. Dales was asked to read from the documents introduced into evidence by counsel for the respondent. Essentially, one of the passages read by Mr. Dales stated that a number of reports had appeared over the last few years in local newspapers in the North of England and Scotland that claimed miraculous results for the treatment of both adult and juvenile rheumatoid arthritis with devil's claw. Another passage stated that, in a certain study, the criterion for admission of devil's claw was the failure of conventional therapy to control the patient's disease activity. Further, in that study, 4 out of 12 patients showed some subjective or objective improvement within certain parameters. Mr. Dales also read certain passages from these documents which stated that devil's claw is an herbal product used as a remedy in the treatment of arthritic symptoms and that, in recent years, it has received wide acceptance in both Canada and Europe as a treatment of arthritic disease.

The appellant's second witness, Ms. Catherine Myerowitz, a pharmacist/nutritional consultant, was qualified as an expert in pharmacy and in the dispensation of herbal medicines, such as devil's claw. She testified that she has a degree in pharmacy, which she obtained in South Africa. It is there that, at one point in her career, she worked as a pharmacist. She testified that, soon after moving to Canada, she worked for the appellant for approximately five years. She explained that the active ingredient in devil's claw seems to be a synergistic combination of the compounds in the extract. Three of the compounds known to exist are harpagoside, harpagide and procumbide. She testified that there are also other compounds which are not known yet. She said that these ingredients have an anti-inflammatory effect. They reduce the inflammation caused by arthritis as well as the pain, stiffness and swelling which come with the inflammation. She testified that arthritis is an illness. She said that devil's claw is used exclusively for therapeutic uses. Finally, she testified that it is a generally accepted fact that there is no cure for the common cold.

In cross-examination, Ms. Myerowitz explained that her knowledge of the effects of devil's claw comes from consultations with other pharmacists and from discussions with many patients who have used the product. She testified that the product does not always work, but that a very high percentage of patients do get relief if they take the medication in the prescribed manner for a long enough period. She said that, in her experience, it usually takes from 4 to 6 weeks for the product to take effect. In her view, even though the package indicates that the product should be taken for 20 weeks, a patient should stop taking it if the symptoms disappear before then. There would, however, be no harm in taking it for 20 weeks. She testified that the benefits of using devil's claw are that it does not have the side effects of other anti-inflammatory drugs.

In answering questions from the Tribunal, Ms. Myerowitz testified that she tells her patients to take devil's claw root 410, because it is a standardized extract, but that she does not mind which one they take. She said that the product has an extremely bitter taste. It used to be even more bitter when it was only available in the form of dried herb to be drunk as an infusion, like tea. It is not as bitter in the tablet form. She testified that, when she worked as a pharmacist, she kept notes to try to find out the length of time it would take for devil's claw to work and how it works. She testified that people who used devil's claw said that it helped their arthritis. She told the story of one woman who, by taking devil's claw for six weeks, was able to resume doing her pottery, which she had stopped doing because of bad arthritis in her hands. She said that, in most cases, the arthritis seems to go away for a while, sometimes for a few years, and then it comes back and people need to repeat the treatment. She testified that, in her view, devil's claw has no nutritional value.

The final witness for the appellant was Mr. Jens Tonnesen, Operations Manager for Flora Distributors Ltd. He testified that he looks after the importation of various products, including the goods in issue, which the appellant has been importing since 1982. He explained that a document entitled "Relieve Your Aching and Stiffness with Devil's Claw,[12]" which was introduced into evidence, is distributed to owners and staff of Canadian health food stores by the appellant's sales representatives during their sales visits or during seminars or conferences. He read passages from this document which said that the "anti-inflammatory and anti-arthritic properties of devil's claw root are generally observed in a few weeks," and that a "remedial course of 3 tablets per day over 3 weeks is recommended." Finally, he testified that the appellant markets and sells devil's claw for the treatment of pain caused by arthritis.

In cross-examination, Mr. Tonnesen testified that the document to which he referred gives the appellant's view on the use of its product. He explained that the document mentions a different recommended dosage than the one provided on the package, because it was written by someone other than a representative of the appellant and was not edited by the appellant. He said that the appellant endorses the document in the broad terms of the medicament. Mr. Tonnesen explained that, three years ago, the product was being imported as a medicinal product and that the appellant was paying 9.5 percent duty. Then, it was agreed internationally that the duty on medicinal products should be reduced to zero. Just after that, the government suddenly started calling the product a food supplement.

In answering questions from the Tribunal, Mr. Tonnesen testified that a package of devil's claw which has a 20-week supply retails for approximately $17.65 per package, while a package which has a 4-week supply retails for approximately $15.95. He said that, since he has been with the appellant, it has received many letters from people who have used devil's claw, none of whom he could recall claimed that the product did not work. He testified that, in his view and in the appellant's view, there is no question that

12. Exhibit A-5.

this product is a medicinal product. He said that the appellant is in the herb business, not the food business. According to Mr. Tonnesen, the health food issue is a misnomer. People just call it that because it is an accepted term. He said that, in health food stores, one finds herbal medicine products and traditional medicine products.

In re-examination, Mr. Tonnesen distinguished the role of the Department of National Revenue, which regulates the importation of products and deals with the issue of classification, and that of Health Canada, which regulates the retail sale of those goods, which is a totally different function.

The appellant's representative argued that tariff classification is determined at the time of importation in accordance with the *Harmonized Commodity Description and Coding System*.[13] He argued that all countries must classify the same goods in the first six digits, irrespective of how their governments administer their drug or food policies. The representative argued that the respondent's classification is incorrect for the following four reasons: (1) the respondent is relying on the *Explanatory Notes to the Harmonized Commodity Description and Coding System*[14] (the Explanatory Notes) to heading No. 30.03 in order to support a classification in heading No. 30.04; (2) the respondent's reliance on the Tribunal's decision in *Upjohn Inter-American Corporation* v. *The Deputy Minister of National Revenue for Customs and Excise*[15] was improper; (3) the respondent's position that, in order to be classified in heading No. 30.04, a product must be shown to be effective is incorrect; and (4) the respondent's interpretation of the Explanatory Notes to heading No. 21.06 is also incorrect.

In support of his first argument that the Explanatory Notes to heading No. 30.03 do not apply to heading No. 30.04, the appellant's representative relied on the Tribunal's decision in *Intercraft Industries of Canada Inc.* v. *The Deputy Minister of National Revenue*.[16] He argued that the Explanatory Notes to one heading do not apply to another heading, unless it is expressly provided that they apply to such heading. In support of his argument, he referred to the Explanatory Notes to heading No. 76.10, which provide that the "provisions of the Explanatory Note to heading 73.08 apply, *mutatis mutandis*, to this heading." Due to the absence of such wording in the Explanatory Notes to heading No. 30.03, the Explanatory Notes to heading No. 30.04 cannot be applied to that heading. The representative noted that heading No. 30.04 applies to medicaments which are put up for retail sale, while heading No. 30.03 applies to medicaments which are sold in bulk. He argued that the two are totally different and that they have different rules that apply to their classification. With respect to his second argument, the representative noted that the *Upjohn* decision dealt with a tariff classification in heading No. 30.03 and, for the reasons noted above, is irrelevant.

The appellant's representative relied on the Tribunal's decision in *Hung Gay Enterprises Ltd.* v. *The Deputy Minister of National Revenue*[17] in support of his third argument that scientific proof of efficacy is not required in order for a product to be classified in heading No. 30.04. He argued that there is no such requirement in Schedule I to the *Customs Tariff* or in the Explanatory Notes. Rather, in his view, they provide the contrary. He noted that "[c]ough and cold preparations" are classified under tariff item No. 3004.90.99 even though there is no known cure for the common cold. The representative argued that to rule in favour of the respondent would mean that drugs for illnesses such as AIDS could not be classified in

13. Customs Co-operation Council, 1st ed., Brussels, 1987.
14. Customs Co-operation Council, 1st ed., Brussels, 1986.
15. Appeal No. AP-90-197, January 20, 1992.
16. Appeal Nos. AP-93-358 and AP-93-353, March 14, 1995.
17. Appeal No. AP-96-044, June 5, 1997.

heading No. 30.04 until there is conclusive scientific proof of their efficacy. He submitted that it would be illogical to classify such a product as a food or something other than a medicament.

According to the appellant's representative, the evidence clearly shows that devil's claw is not a food and, therefore, cannot be classified in heading No. 21.06. He referred to the evidence which showed that this product has no nutritional value. In support of this argument, he referred to the Tribunal's decision in *Shaklee Canada Inc.* v. *The Minister of National Revenue*,[18] which was upheld by the Federal Court of Canada.[19] In that case, it was held that goods similar to the ones in issue were dietary supplements or nutritional supplements and not food. He referred to the Tribunal's decision in *Baxter Corporation* v. *The Deputy Minister of National Revenue*[20] to support his argument that heading No. 21.06 provides for the classification of ordinary food or mixtures used in the preparation of such foods.

In support of his argument, the appellant's representative referred to paragraph 16 of the Explanatory Notes to heading No. 21.06, which provides that food preparations or supplements which are intended for the prevention or treatment of disease or ailments are excluded from that heading and must be classified in heading No. 30.03 or 30.04. He argued, that because devil's claw is intended for the prevention of a disease or ailment, it cannot be classified in heading No. 21.06. According to the representative, the evidence shows that arthritis is a disease. He relied on the Explanatory Notes to heading No. 30.04 in support of his argument that, since devil's claw is a medicament, which is put up for retail sale, it must be classified in that heading. The Explanatory Notes also provide that, where medicaments are put up in measured doses such as tablets, they must be classified in heading No. 30.04. He argued that the goods in issue meet this requirement. According to the representative, the Explanatory Notes do not require that the intended use be printed on the label. It can be indicated in the literature or in any other way. He argued that, in any event, the recommended use of devil's claw is indicated on the package. Finally, he referred to the Explanatory Note to heading No. 30.04, which provides that food supplements are excluded from that heading.

Counsel for the respondent argued that the appellant must prove that the product is an effective remedy for arthritis for it to be considered a medicament for therapeutic or prophylactic use. He argued that the appellant has not done so in the present case and that its appeal should, therefore, be dismissed. In other words, the goods in issue cannot be classified in heading No. 30.04. Counsel submitted that the following three requirements must be met in order for a product to be classified in heading No. 30.04: (1) the product must be a medicament; (2) it must consist of mixed or unmixed products for therapeutic or prophylactic uses; and (3) it has to be put up in measured doses or in forms of packing for retail sale. Counsel relied on the Tribunal's decision in *Upjohn* with respect to the meaning to be attributed to the words "medicament," "therapeutic" and "prophylactic." Counsel argued that the case is relevant even though it dealt with heading No. 30.03 instead of heading No. 30.04, because the words used in the two headings are the same. The only difference is that one heading deals with products which are put up in measured doses or in packings for retail sale. In counsel's view, this does not affect the meaning to be attributed to the words "medicament," "therapeutic" or "prophylactic."

In *Upjohn*, the Tribunal interpreted heading No. 30.03 as referring to substances used to treat or prevent disease, or medicinal preparations used to treat or prevent sickness. In the view of counsel for the

18. Appeal No. 2940, September 6, 1990.
19. *Shaklee Canada Inc.* v. *Her Majesty the Queen*, Court File No. T-3012-90, February 28, 1995.
20. Appeal No. AP-93-092, July 26, 1994.

respondent, the appellant must show conclusive scientific evidence that goods are used to treat or prevent a disease in order to be classified as a "medicament." He argued that "treat" does not equate "cure." He said that there is no question that there is no "cure" for the common cold. However, there are medicines which treat or relieve the symptoms of the common cold, for example antihistamines, decongestants or any kind of drug to reduce fever. Therefore, they are a treatment for the disease, but not a cure. He argued that there are drugs that do the same thing for arthritis. They do not cure arthritis, but they relieve the symptoms. Counsel submitted that it does not matter whether something cures the disease. The key is that it has to be shown to treat it.

Counsel for the respondent argued that the reason that it is important to have scientific proof of the efficacy of a product in order for it to be classified in heading No. 30.04 is that it does not become wide open, allowing importers to bring in anything in that heading that they claim has a medicinal use. He said that, if proof of efficacy is not required, then an importer would simply have to claim that a product is used in the treatment of a disease and that it is put up in doses for retail sale, in order to fall within heading No. 30.04. In counsel's view, this is clearly wrong. He referred to the Explanatory Notes to heading No. 30.04 in support of his argument that efficacy needs to be proven in order for a product to be classified therein. He argued that the Explanatory Notes provide that a product must contain medicinal properties in such a proportion as to give them therapeutic or prophylactic uses in order to be classified in heading No. 30.04. He argued that the product must do some good. Furthermore, counsel argued that herbal infusions which claim to provide relief from ailments or contribute to the general health and well-being, but which do not constitute a therapeutic or prophylactic dose of an active ingredient, are excluded from heading No. 30.04.

According to counsel for the respondent, there was no evidence presented that devil's claw contains an active ingredient effective in the treatment of arthritis. Counsel reviewed the evidence and argued that it shows that the effectiveness of the goods in issue still remains inconclusive. He said that there are studies which show that devil's claw alleviates some symptoms of arthritis, while others show it to be ineffective. He referred to a particular study which showed that devil's claw is only effective when it is injected into the abdomen of mice, but not slightly active with oral administration. Counsel also noted that many of the studies presented into evidence were paid for by the manufacturers of devil's claw products. He argued that devil's claw is similar to products such as ginseng, evening primrose oil and aqueous ethanol solutions of various herbs which are all classified under the "food" headings. He referred to the *Compendium of Classification Opinions to the Harmonized Commodity Description and Coding System*[21] (the Classification Opinions) in support of this argument. One Classification Opinion provided that "[n]icotine chewing gum" is classified in subheading No. 2106.90. He noted that the evidence on record in this appeal shows that nicotine gum has no nutritional value. Counsel referred to the evidence which shows that there were three different recommended doses for devil's claw. He argued that this was so because the effective dose is not known.

Counsel for the respondent argued that the Tribunal's decision in *Hung Gay* is distinguishable from the present case on the basis that, in *Hung Gay*, the Tribunal found that the product in issue was a "tonic" and, therefore, on that basis, was excluded from heading No. 30.04. As for the Tribunal saying that efficacy need not be proven in order for a product to be classified in heading No. 30.04, counsel argued that the Tribunal was wrong. Finally, counsel argued that the *Shaklee* case could be distinguished on the basis that

21. Customs Co-operation Council, 1st ed., Brussels, 1987.

the Tribunal and the Federal Court of Canada in that case were dealing with an exemption under the *Excise Tax Act*[22] and not a tariff classification under the *Customs Act*.

When classifying goods in Schedule I to the *Customs Tariff*, the application of Rule 1 of the *General Rules for the Interpretation of the Harmonized System*[23] (the General Rules) is of the utmost importance. Rule 1 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 Explanatory Notes.

Heading No. 21.06 provides for the classification of "[f]ood preparations not elsewhere specified or included." The Explanatory Notes to heading No. 21.06 further provide that "[p]reparations, often referred to as *food supplements*, based on extracts from plants, fruit concentrates, honey, fructose, etc. and containing added vitamins … 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)." In the Tribunal's view, the goods in issue are not included in the common understanding given to the term "food preparations." The Tribunal relies on its decision in *Shaklee* in support of this decision. The goods in issue in that case were certain vitamins, minerals and fibre products. Applying the test enunciated in *Shaklee*, the Tribunal is of the view that the person on the street, being well informed of the prescribed conditions and dictionary definitions, would not conclude that the goods in issue are "food." The evidence shows that the goods in issue would not be eaten as "food" because they are bad tasting and that there would be serious side effects in doing so. Further, there is no evidence before the Tribunal to allow it to conclude that the goods in issue are "food supplements." Indeed, the evidence shows that they have no nutritional value. Therefore, the goods in issue cannot be classified under tariff item No. 2106.90.99.

Heading No. 30.04 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." In *Baxter Corporation*, the Tribunal relied on 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.'"

The Tribunal accepts the evidence of the appellant's witnesses that devil's claw is used in the treatment of arthritis, which is a disease or an illness. The Tribunal attributes particular weight to the testimony of Ms. Myerowitz, a pharmacist with many years of experience in dealing with patients who have used the goods in issue, who explained that the ingredients in devil's claw act as an anti-inflammatory and reduce pain, stiffness and swelling caused by arthritis. The Tribunal is, therefore, of the view that the goods in issue can be described as a medicament. The Tribunal agrees with the appellant's representative that there is no requirement in the relative Chapter Notes, the Explanatory Notes or the terms of the heading that a product must be scientifically proven to be an effective medicament in order to be classified in heading No. 30.04. In other words, it does not need to be shown that a product actually cures a disease or illness.

22. R.S.C. 1985, c. E-15.
23. *Supra* note 2, Schedule I.

However, in the Tribunal's view, there must be some "curative" properties shown in order for a product to be accepted as being used in the treatment of a disease and for it to be classified in heading No. 30.04. The word "curative" is defined in the *New Lexicon Webster's Dictionary of the English Language* as "having remedial properties, helping to cure.[24]" In the Tribunal's view, the appellant has met that burden in the present case. The goods in issue have remedial properties which help "cure" or "treat" arthritis.

The Tribunal notes that the evidence shows that the goods in issue are "put up in measured doses or in forms or packings for retail sale," as specified by the terms of heading No. 30.04.

All of the conditions of heading No. 30.04 having 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.

Raynald Guay
Raynald Guay
Presiding Member

Patricia M. Close
Patricia M. Close
Member

Arthur B. Trudeau
Arthur B. Trudeau
Member

24. (New York: Lexicon Publications, 1987) at 236.