CANADIAN INTERNATIONAL TRADE TRIBUNAL
TRIBUNAL CANADIEN DU COMMERCE EXTÉRIEUR

Ottawa, Wednesday, September 29, 1993

Appeal No. AP-92-087

IN THE MATTER OF an appeal heard on March 23, 1993, under subsection 67(1) of the *Customs Act*, R.S.C. 1985, c. 1 (2nd Supp.);

AND IN THE MATTER OF two decisions of the Deputy Minister of National Revenue for Customs and Excise dated May 14 and July 21, 1992, with respect to requests for re-determination under subsection 63(1) of the *Customs Act*.

BETWEEN

APOTEX INC. **Appellant**

AND

THE DEPUTY MINISTER OF NATIONAL REVENUE FOR CUSTOMS AND EXCISE **Respondent**

DECISION OF THE TRIBUNAL

The appeal is dismissed.

Lise Bergeron
Lise Bergeron
Presiding Member

Michèle Blouin
Michèle Blouin
Member

Desmond Hallissey
Desmond Hallissey
Member

Michel P. Granger
Michel P. Granger
Secretary

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CANADIAN INTERNATIONAL TRADE TRIBUNAL | TRIBUNAL CANADIEN DU COMMERCE EXTÉRIEUR

UNOFFICIAL SUMMARY

Appeal No. AP-92-087

APOTEX INC. **Appellant**

and

THE DEPUTY MINISTER OF NATIONAL REVENUE FOR CUSTOMS AND EXCISE **Respondent**

This is an appeal under subsection 67(1) of the Customs Act from decisions of the Deputy Minister of National Revenue for Customs and Excise dated May 14 and July 21, 1992. The issue in this appeal is whether the product described as "Captopril USP powder" imported from Spain by the appellant meets the required conditions of tariff code 6350 of the Customs Duties Reduction or Removal Order, 1988, No. 1 and, thereby, qualifies for duty-free entry into Canada.

HELD: *The appeal is dismissed. The appellant was not able to demonstrate that the Captopril USP powder meets the requirements set out in tariff code 6350 of the Customs Duties Reduction or Removal Order, 1988, No. 1.*

Place of Hearing:	*Ottawa, Ontario*
Date of Hearing:	*March 23, 1993*
Date of Decision:	*September 29, 1993*
Tribunal Members:	*Lise Bergeron, Presiding Member* *Michèle Blouin, Member* *Desmond Hallissey, Member*
Counsel for the Tribunal:	*Shelley Rowe*
Clerk of the Tribunal:	*Dyna Côté*
Appearance:	*Gilles Villeneuve, for the respondent*

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CANADIAN INTERNATIONAL TRADE TRIBUNAL
TRIBUNAL CANADIEN DU COMMERCE EXTÉRIEUR

Appeal No. AP-92-087

APOTEX INC. **Appellant**

and

THE DEPUTY MINISTER OF NATIONAL REVENUE FOR CUSTOMS AND EXCISE **Respondent**

TRIBUNAL: LISE BERGERON, Presiding Member
MICHÈLE BLOUIN, Member
DESMOND HALLISSEY, Member

REASONS FOR DECISION

This is an appeal under subsection 67(1) of the *Customs Act*[1] (the Act) from two decisions of the Deputy Minister of National Revenue for Customs and Excise dated May 14 and July 21, 1992. The issue in this appeal is whether the product described as "Captopril USP powder" imported from Spain by the appellant meets the required conditions of tariff code 6350 of the *Customs Duties Reduction or Removal Order, 1988, No. 1*[2] (the Order) and, thereby, qualifies for duty-free entry into Canada.

The appellant did not appear at the hearing, but filed a brief with the Tribunal. Counsel for the respondent made preliminary remarks regarding the appellant's burden of proving that the subject product met the requirements of tariff code 6350 and submitted, on the basis of the Tribunal's decision in *Unicare Medical Products Inc. v. The Deputy Minister of National Revenue for Customs and Excise*,[3] that the appeal should be dismissed. The Tribunal decided that it would consider the appellant's submissions and give them whatever weight that it thought was appropriate in accordance with rule 22 of the *Canadian International Trade Tribunal Rules*.[4] On that basis, counsel for the respondent chose to proceed to present his evidence.

For ease of reference, the relevant tariff classification nomenclature of the *Customs Tariff*[5] for this appeal is reproduced below:

Code 6350	*Single amino-acids of heading No. 29.22, 29.30 or 29.33 for use in the manufacture of mixtures of amino-acids or of mixtures of amino-acids and protein hydrolysates of tariff item No. 3003.90.10, 3004.50.10 or 3004.90.10*
29.33	*Heterocyclic compounds with nitrogen hetero-atom(s) only; nucleic acids and their salts.*
2933.90.00	*-Other*
2933.90.00.14	*------Captopril*

1. R.S.C. 1985, c. 1 (2nd Supp.).
2. SOR/88-73, December 31, 1987, Canada Gazette Part II, Vol. 122, No. 2 at 631.
3. (1990) 3 T.T.R. 152, Appeal Nos. 2437, 2438, 2485, 2591 and 2592, April 30, 1990.
4. SOR/91-499, August 14, 1991, Canada Gazette Part II, Vol. 125, No. 18 at 2912.
5. R.S.C. 1985, c. 41 (3rd Supp.).

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30.03 *Medicaments (excluding goods of heading No. 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.*

3003.90 *-Other*

3003.90.10 *---Fractionated soya oil emulsions, prepared for parenteral administration; mixtures of amino acids and mixtures of amino acids and protein hydrolysates, whether or not containing added minerals, vitamins, fats or carbohydrates, specially compounded for persons afflicted with amino acid disorders; dextrose (glucose) solutions and levulose (fructose) solutions, prepared for parenteral administration*

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.*

3004.50 *-Other medicaments containing vitamins or other products of heading No. 29.36*

3004.50.10 *---Mixtures of amino acids and vitamins, and mixtures of amino acids, protein hydrolysates and vitamins, whether or not containing added minerals, fats or carbohydrates, specially compounded for persons afflicted with amino acid disorders*

3004.90 *-Other*

3004.90.10 *---Mixtures of amino acids and mixtures of amino acids and protein hydrolysates, whether or not containing added minerals, fats or carbohydrates, specially compounded for persons afflicted with amino acid disorders; liver extracts, pituitary extracts, fractionated soya oil emulsions, dextrose (glucose) solutions and levulose (fructose) solutions, prepared for parenteral administration*

Counsel for the respondent reviewed for the Tribunal the qualifications of Mr. Wendell Ward, of the Analytical Section of the Organics/Food Laboratory of the Department of National Revenue, following which the Tribunal decided to accept Mr. Ward as an expert in the field of chemistry. Mr. Ward agreed with the following definition of amino acid as provided in the excerpt from Organic Chemistry[6] in the appellant's brief:

> *The term amino acid indicates that the monomer contains an amine group and an acid group, specifically a carboxylic acid group.*

Mr. Ward stated that, based on his analysis, the Captopril USP powder and the processed form of the powder, Captopril tablets, do not constitute amino acids. The Captopril USP powder contains only an acid group and contains no amine group. The Captopril tablets do not contain amino acids or protein hydrolysates. Mr. Ward produced as Exhibit B-2 the Report of the Laboratory and Scientific Services Directorate,[7] which he prepared to document these conclusions.

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6. Philip S. Bailey Jr. and Christina A. Bailey, 4th ed. (Boston: Allyn and Bacon, 1989) at 429.
7. Department of National Revenue, Customs and Excise, February 11, 1992.

Mr. Ward explained that he reached these conclusions after having analyzed the Captopril USP powder and the Captopril tablets. He used four methods to analyze the Captopril USP powder: Gas Chromatography Mass Spectroscopy (GCMS test); Nuclear Magnetic Residence Spectroscopy; Carbon Hydrogen Nitrogen Analysis; and Infrared Spectrum. The general purpose of all the tests was to determine the structure and elements of the Captopril USP powder. With the exception of the Nuclear Magnetic Residence Spectroscopy test, Mr. Ward used the same methods to analyze the Captopril tablets. He also conducted a microscopic examination.

Finally, Mr. Ward examined an illustration of the chemical structure of Captopril attached to the appellant's brief and stated that, in his opinion, Captopril could not be called an amino acid because, as a result of the chemical reaction, it no longer contained an amine group.

The respondent's second witness, Dr. René Roy, currently an associate professor of the Chemistry Department at the University of Ottawa, and cross-appointed to the Department of Microbiology and Immunology Health Sciences at the University of Ottawa, was also qualified by the Tribunal as an expert in the field of organic chemistry. Dr. Roy explained that, in his opinion, an amino acid must be composed of both an amine group and a carboxylic group, and he introduced as Exhibit B-5 an excerpt from The Vocabulary of Organic Chemistry[8] in support of the use of this definition. He stated that this definition was shared and accepted by the international community of pure and applied chemists and is used in every chemistry class in a university environment. Dr. Roy also referred to the definition of amino acid in The Oxford English Dictionary,[9] which, in his view, corresponds to the definition from The Vocabulary of Organic Chemistry.

When asked by counsel for the respondent to comment on the methods employed by Mr. Ward to analyze the product, Dr. Roy responded that these are the standard methods used by analysts to determine the structure of a chemical.

Counsel for the respondent asked Dr. Roy to look at the same illustration of the chemical reaction required to produce Captopril, which was examined by Mr. Ward. Dr. Roy reached the same conclusion as Mr. Ward, i.e. that the Captopril was not an amino acid since it did not contain an amine group.

The appellant's position, as indicated in its brief, is that, although Captopril is used for the treatment of hypertension and heart failure, it is also used in the treatment of cystinuria, which is an amino acid disorder. To support this view, the appellant has filed a letter from Dr. Elizabeth Harvey, MD FRCPC of the Toronto Hospital for Sick Children.

Further, the appellant submitted that tariff code 6350 does not exclude the use of the final product as a hypertension medicament, but stated that it must be capable of treating amino acid disorders. Since Captopril is capable of treating cystinuria, an amino acid disorder, it meets the requirements of tariff code 6350.

Counsel for the respondent argued that, in order to meet the required conditions of tariff code 6350, the product in issue, the Captopril USP powder, must be: a single amino acid of heading No. 29.22, 29.30 or 29.33; used in the manufacture of mixtures of amino acids or of mixtures of amino acids and protein hydrolysates; and used in the manufacture of a product listed under tariff item No. 3003.90.10, 3004.50.10 or 3004.90.10. Counsel for the respondent relied

8. Milton Orchin *et al.* (New York: John Wiley & Sons, 1980) at 173.
9. Volume I, 2nd ed. (Oxford: Clarendon Press, 1989) at 403.

on the results of the laboratory analysis of Mr. Ward and the testimony of Dr. Roy to support his argument that the product in issue does not meet any of these requirements.

With respect to the first requirement, counsel for the respondent relied on the evidence and report of Mr. Ward and Dr. Roy that Captopril is not a single amino acid, but is a derivative of an amino acid. It is a synthetic chemical that has been manufactured from the amino acid, L-proline. Counsel submitted that, during the manufacturing process, the chemical structure is changed so that it is no longer an amino acid. In the view of counsel for the respondent, Captopril should continue to be classified in heading No. 29.33 because it is a compound with a heterocyclic ring containing nitrogen.

Counsel for the respondent submitted that the Captopril USP powder is not used in the manufacture of mixtures of amino acids or mixtures of amino acids and protein hydrolysates, since it is used to manufacture Captopril tablets composed of Captopril and microcrystalline cellulose filler. These tablets do not contain either amino acids or protein hydrolysates.

Finally, counsel for the respondent argued that all of the products listed under tariff item Nos. 3003.90.10, 3004.50.10 and 3004.90.10 are for use by persons afflicted with amino acid disorders. However, according to Martindale's The Extra Pharmacopoeia,[10] Captopril is used in the treatment of severe hypertension and congestive heart failure and is, therefore, not "specially compounded for persons afflicted with amino acid disorders" as set out in tariff item Nos. 3003.90.10 and 3004.90.10.

In order for the Captopril USP powder to qualify for duty-free entry into Canada, the appellant must demonstrate that it meets the requirements set out in tariff code 6350 of the Order. The first requirement is that the product must be a "single amino-acid of heading No. 29.22, 29.30 or 29.33." After having heard the evidence of Mr. Ward and Dr. Roy, who are accepted by the Tribunal as experts in the field of organic chemistry, the Tribunal is of the view that Captopril USP powder is not an amino acid, since it does not contain an amine group. Given that the Captropril USP powder does not meet the first requirement of tariff code 6350, the Tribunal does not find it necessary to consider the other requirements of that code. The Tribunal finds that the Captopril USP powder does not qualify for duty-free status under tariff code 6350 and, accordingly, this appeal is dismissed.

Lise Bergeron
Lise Bergeron
Presiding Member

Michèle Blouin
Michèle Blouin
Member

Desmond Hallissey
Desmond Hallissey
Member

10. Martindale, 28th ed. (London: Pharmaceutical Press, 1982) at 138.