

Ottawa, Friday, October 27, 1995

**Appeal No. AP-94-185**

IN THE MATTER OF an appeal heard on February 13, 1995,  
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 June 17 and July 20, 1994, with respect to  
requests for re-determination under section 63 of the *Customs Act*.

**BETWEEN**

**HOECHST CANADA INC.**

**Appellant**

**AND**

**THE DEPUTY MINISTER OF NATIONAL REVENUE**

**Respondent**

**DECISION OF THE TRIBUNAL**

The appeal is allowed.

Lise Bergeron  
Lise Bergeron  
Presiding Member

Arthur B. Trudeau  
Arthur B. Trudeau  
Member

Charles A. Gracey  
Charles A. Gracey  
Member

Michel P. Granger  
Michel P. Granger  
Secretary

**UNOFFICIAL SUMMARY**

**Appeal No. AP-94-185**

**HOECHST CANADA INC.**

**Appellant**

**and**

**THE DEPUTY MINISTER OF NATIONAL REVENUE**

**Respondent**

*The appellant is an importer and distributor of pharmaceutical products, including the product in issue, Ultracaine, which is a local anaesthetic used in dentistry. The issue in this appeal is whether the product in issue is properly classified under tariff item No. 3004.39.99 as other medicaments for human use, as determined by the respondent, or should be classified under tariff item No. 3004.39.10 as epinephrine and its solutions and pituitary extracts, prepared for parenteral administration, as claimed by the appellant.*

***HELD:** The appeal is allowed. The Tribunal is of the view that the wording of tariff item No. 3004.39.10 does not require that goods classified under that tariff item have epinephrine as its main active ingredient. Furthermore, classification at that level is subject to the wording “[c]ontaining hormones or other products of heading No. 29.37 but not containing antibiotics” and, in particular, to the word “[c]ontaining” which appears at the subheading level of heading No. 30.04. In the Tribunal’s view, the implication of these two factors is that goods that contain any amount of epinephrine may be classified under tariff item No. 3004.39.10, as long as they satisfy the other conditions of the heading, subheading and tariff item and related legal notes. The Tribunal finds that these other conditions are also satisfied and, therefore, that the product in issue should be classified under tariff item No. 3004.39.10.*

*Place of Hearing: Ottawa, Ontario  
Date of Hearing: February 13, 1995  
Date of Decision: October 27, 1995*

*Tribunal Members: Lise Bergeron, Presiding Member  
Arthur B. Trudeau, Member  
Charles A. Gracey, Member*

*Counsel for the Tribunal: Hugh J. Cheetham*

*Clerk of the Tribunal: Anne Jamieson*

*Appearances: Michael A. Sherbo, for the appellant  
Stéphane Lilkoff, for the respondent*

**Appeal No. AP-94-185**

**HOECHST CANADA INC.**

**Appellant**

**and**

**THE DEPUTY MINISTER OF NATIONAL REVENUE**

**Respondent**

TRIBUNAL: LISE BERGERON, Presiding Member  
ARTHUR B. TRUDEAU, Member  
CHARLES A. GRACEY, Member

**REASONS FOR DECISION**

This is an appeal under section 67 of the *Customs Act*<sup>1</sup> (the Act) from decisions of the Deputy Minister of National Revenue dated June 17 and July 20, 1994.

The appellant is an importer and distributor of pharmaceutical products, including the product in issue, Ultracaine, which is a local anaesthetic used in dentistry. The product in issue was imported in a number of transactions occurring between 1992 and 1994 and was classified under tariff item No. 3004.39.99 of Schedule I to the *Customs Tariff*<sup>2</sup> as other medicaments for human use. The appellant filed requests for re-determination of the classification under tariff item No. 3004.39.10 as epinephrine and its solutions and pituitary extracts, prepared for parenteral administration. These requests were rejected. The appellant subsequently filed further requests for re-determination and, by decisions dated June 17 and July 20, 1994, the respondent maintained the classification of the product in issue under tariff item No. 3004.39.99.

The issue in this appeal is whether the product in issue is properly classified under tariff item No. 3004.39.99 as other medicaments for human use, as determined by the respondent, or should be classified under tariff item No. 3004.39.10 as epinephrine and its solutions and pituitary extracts, prepared for parenteral administration, as claimed by the appellant.

The relevant provisions of the *Customs Tariff* read as follows:

30.04	<i>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 packing for retail sale.</i>
	<i>-Containing hormones or other products of heading No. 29.37 but not containing antibiotics:</i>
3004.31	<i>--Containing insulin</i>
3004.32	<i>--Containing adrenal cortical hormones</i>
3004.39	<i>--Other</i>
3004.39.10	<i>---Epinephrine and its solutions and pituitary extracts, prepared for parenteral administration</i>

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

---Other:  
3004.39.99 ---Other

At the outset of the hearing, the Tribunal requested that the parties confirm what appeared to be agreement between the parties with respect to a number of factual matters relating to the issue in this appeal. The parties agreed that epinephrine is: (1) present to enhance the effect of articaine in the product in issue; (2) a secondary active ingredient in the product in issue; and (3) a hormone or product of heading No. 29.37.

The appellant's representative called one witness, Mr. Kristof Biniecki, Quality Assurance Manager for Hoechst Canada Inc. Mr. Biniecki was Quality Assurance Manager for Roussel Canada Inc. (Roussel) from 1980 until the merger of Roussel with the appellant two years ago. Since the merger, he has been in his present position. In this capacity, Mr. Biniecki is responsible for ensuring that the product in issue is manufactured in accordance with relevant regulations and practices, through quality control analysis of the product in issue after it is imported. He is also responsible for releasing the products which he oversees onto the Canadian market.

Mr. Biniecki stated that the product in issue contains two active ingredients: (1) articaine, a local anaesthetic which temporarily blocks the propagation of impulses along nerves and also stops pain penetration in the area being worked on; and (2) epinephrine or adrenaline, which acts as a vasoconstrictor and acts to constrict blood flow, allowing for a higher concentration of articaine to remain around a nerve for a longer period of time. In other words, the epinephrine prolongs the effects of the articaine. When asked to describe the amount of epinephrine contained in the product in issue, Mr. Biniecki agreed that the concentration was the amount needed to perform the function desired in this drug.

In response to questions from the Tribunal, Mr. Biniecki confirmed that the product in issue is used only in dentistry. He also stated that "parenteral administration" means administration by means of injection.

Counsel for the respondent called two witnesses. The first witness was Mr. Wendell Ward, who is Head of the Analytical Section of the Organics/Foods Laboratory of the Department of National Revenue. Mr. Ward was accepted by the Tribunal as an expert in chemistry. Mr. Ward confirmed that he had analyzed the product in issue and found that it contained a small quantity of epinephrine, namely, 1 part per 100,000. Mr. Ward also confirmed his witness statement, in which he set out a number of products that he considered to be "[e]pinephrine and its solutions." The list was compiled from the Compendium of Pharmaceuticals and Specialties.<sup>3</sup> It did not include the product in issue.

In response to questions from the Tribunal, Mr. Ward indicated that he knew of nothing in the Explanatory Notes to the Harmonized Commodity Description and Coding System<sup>4</sup> (the Explanatory Notes) which provides that a product should or should not be classified as epinephrine on the basis of the concentration of epinephrine in such a product. Mr. Ward also stated that he would classify the product in issue as "[o]ther" because he was of the opinion that it is a solution of articaine and could not be described as "[e]pinephrine and its solutions."

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3. Twenty-ninth ed. (Ottawa: Canadian Pharmaceutical Association, 1994).

4. Customs Co-operation Council, 1st ed., Brussels, 1986.

Counsel for the respondent's second witness was Professor Pavel D. Hrdina. Professor Hrdina has been a professor of Pharmacology at the University of Ottawa for 25 years. The Tribunal accepted Professor Hrdina as an expert in neuropharmacology.

Professor Hrdina stated that an active ingredient in a drug is a component of the drug which produces an active pharmacological effect when administered in the body. A major active ingredient gives the drug a characteristic which defines the use of the drug. A minor active ingredient could be any compound which either helps the effectiveness or combats side effects of the main ingredient. With respect to the product in issue, the main active ingredient is articaine, which is a local anaesthetic, and the minor active ingredient is epinephrine, which is present in small amounts and acts as a vasoconstrictor.

In Professor Hrdina's opinion, the expression "[e]pinephrine and its solutions" would relate to a drug or preparation which contains epinephrine as its main active ingredient. He then identified certain products to which the expression would apply. In Professor's Hrdina's view, the product in issue is not described by the expression "[e]pinephrine and its solutions" because its main active ingredient is articaine, which gives it the character of a local anaesthetic.

During cross-examination, Professor Hrdina agreed that the product in issue contains epinephrine and that the epinephrine produces the desired effect. He also agreed that the product in issue is for parenteral administration. In response to questions from the Tribunal, Professor Hrdina stated that, while the epinephrine may be considered important to the product in issue because it helps enhance the duration of the anaesthetic, he did not consider epinephrine essential to the product in issue because it would still act as an anaesthetic if the epinephrine were not present.

The Tribunal notes that the parties are agreed as to the classification of the product in issue in heading No. 30.04 and subheading No. 3004.39. They disagree, however, as to the proper classification at the eight-digit level. Thus, it is agreed that the product in issue is a medicament "[c]ontaining hormones or other products of heading No. 29.37."

The subheadings at the two-dash level under the wording "[c]ontaining hormones or other products of heading No. 29.37 but not containing antibiotics" consist of three categories, namely, "[c]ontaining insulin" (subheading No. 3004.31), "[c]ontaining adrenal cortical hormones" (subheading No. 3004.32) and "[o]ther" (subheading No. 3004.39). In both the testimony of the witnesses and argument, there was much discussion as to the meaning and scope of the term "[o]ther." In the Tribunal's view, in this context, the word "[o]ther" can only refer to the type of goods classifiable in subheading No. 3004.39. In other words, the notation "[o]ther" for subheading No. 3004.39 refers to any medicament of heading No. 30.04 which contains hormones or other products of heading No. 29.37 that does not contain antibiotics, insulin or adrenal cortical hormones.

"Epinephrine and its solutions and pituitary extracts, prepared for parenteral administration" is then found in this subheading at the eight-digit level as tariff item No. 3904.39.10. In the Tribunal's opinion, the product in issue is fully described by this tariff item because the evidence shows that it is a medicament containing a hormone, which is neither insulin nor the adrenal cortical hormone of subheading No. 3004.31 or 3004.32, but which is an "[o]ther" hormone of heading No. 29.37, specifically epinephrine.

Counsel for the respondent submitted that, because the epinephrine contained in the product in issue is present in only a very small concentration and that it cannot be described in pharmacological terms as "[e]pinephrine and its solutions," it should not be classified under tariff item No. 3004.39.10. The Tribunal

does not accept this position because it is persuaded that the evidence is clear that the product in issue contains epinephrine, and there is no requirement or direction in the wording in the heading, subheading, tariff item, Chapter or Section Notes or Explanatory Notes which sets out a minimum concentration below which a product could not be classified as “[e]pinephrine and its solutions.”

Counsel for the respondent also argued that the evidence shows that the phrase “[e]pinephrine and its solutions” has a specific pharmacological meaning, namely, it describes a product in which epinephrine is the main active ingredient. He submitted that, as epinephrine is not the main active ingredient in the product in issue, it cannot be classified under the tariff item suggested by the appellant. There is no doubt as to the meaning of the phrase “[e]pinephrine and its solutions” given by Professor Hrdina as an expert in pharmacology. However, the Tribunal is not persuaded that the tariff item at issue should be interpreted on this basis. The Tribunal agrees with the appellant’s representative that the respondent has agreed that the product in issue should be classified at the four- and six-digit levels on the basis of its content and then, in effect, attempts to classify it at the eight-digit level on a different basis, i.e. end use.

This approach overlooks the fact that the wording of the tariff item does not require that, for a product to be classified under that tariff item, such a product must have epinephrine as its main active ingredient. Furthermore, this approach overlooks the fact that the words “[c]ontaining hormones or other products of heading No. 29.37 but not containing antibiotics” and, in particular, the word “[c]ontaining” apply to the classification of any goods which may be classified below the subheading level. In the Tribunal’s view, the implication of these two factors is that goods that contain any amount of epinephrine may be classified under tariff item No. 3004.39.10, as long as they satisfy the other conditions of the heading, subheading and tariff item and related legal notes. As discussed above, the product in issue does satisfy these other conditions and, therefore, should be classified under tariff item No. 3004.39.10.

Accordingly, the appeal is allowed.

Lise Bergeron  
Lise Bergeron  
Presiding Member

Arthur B. Trudeau  
Arthur B. Trudeau  
Member

Charles A. Gracey  
Charles A. Gracey  
Member