OPINION OF ADVOCATE GENERAL ELMER

delivered on 20 March 1997 *

Introduction

1. Are 'Alvityl 50 Dragées' and 'Strongenol 20 Ampoules' food preparations within the meaning of Chapter 21 of the Common Customs Tariff [1] or are they 'pharmaceutical products' within the meaning of Chapter 30 thereof?

That is the question on which the Court is asked to give a ruling in the present case.

The relevant provisions of Community law

2. *Chapter 21 of the Customs Tariff* covers 'miscellaneous edible preparations'.

Note 1(f) in the introduction to this chapter reads as follows:

'1. This chapter does not cover:

(f) yeast put up as a medicament or other products of heading No 3003 or 3004'.

Heading No 21.06 covers 'food preparations not elsewhere specified or included'.

3. *Chapter 30 of the Customs Tariff* covers 'pharmaceutical products'.

* Original language: Danish.

1 — Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ 1987 L 256, p. 1).

Note 1(a) in the introduction to Chapter 30 reads as follows:

'1. This chapter does not cover:

(a) foods or beverages (such as dietetic, diabetic or fortified foods, food supplements, tonic beverages and mineral waters (Section IV)'.

Heading No 30.04 comprises 'medicaments ... consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packings for retail sale'.

The Explanatory Notes of the Customs Cooperation Council relating to heading No 30.04 include the following information:

'The provisions of the heading text do *not* apply to foodstuffs or beverages such as dietetic, diabetic or fortified foods, tonic beverages or mineral waters (natural or artificial), which fall to be classified under their own appropriate headings. This is essentially the case as regards food preparations containing only nutritional substances. The major nutritional substances in food are proteins, carbohydrates and fats. Vitamins and mineral salts also play a part in nutrition.

...

Further, this heading *excludes* food supplements containing vitamins or mineral salts which are put up for the purpose of maintaining health or well-being but have no indication as to use for the prevention or treatment of any disease or ailment. These products, which are usually in liquid form, but may also be put up in powder or tablet form, are generally classified in heading 21.06 or Chapter 22.'

4. Commission Regulation (EEC) No 210/85 of 25 January 1985 classifying goods in subheading 21.07 G I d) 1 of the Common Customs Tariff [2] ('Regulation No 210/85') provides as follows, so far as relevant:

'[Those products which] have the characteristics of food supplements containing vitamins and mineral salts and intended to keep

2 — OJ 1985 L 24, p. 11, as amended by Commission Regulation (EEC) No 2723/90 of 24 September 1990 replacing the codes established on the basis of the Common Customs Tariff nomenclature in force on 31 December 1987 with those established on the basis of the Combined Nomenclature in certain regulations concerning the classification of goods (OJ 1990 L 261, p. 24).

the body in good health and should be regarded as food preparations [fifth recital in the preamble].

...

Article 1

The following products for sale by retail:

(a) pills having the following composition (per pill):

— vitamin A	2 000 IU
— vitamin C	60 mg
— vitamin D	200 IU
— vitamin E	12 IU
— vitamin B1	1.1 mg
— vitamin B2	1.2 mg
— vitamin B6	2 mg
— niacinamide	13 mg
— calcium pentothenate	4.3 mg
— vitamin B12	3 mcg
— folic acid	50 mcg [3]
— biotin	100 mcg
— iron	10 mg
— zinc	7.5 mg
— manganese	2 mg
— copper	1 mg
— molybdenum	150 mcg
— iodine	75 mcg
— selenium	50 mcg
— chromium	50 mcg
— sucrose (including invert sugar expressed as sucrose)	33%
— water approximately	7%

...

shall be classified in the Common Customs Tariff under subheading No 2106 90 99 ...'.

5. Council Regulation (EEC) No 1010/86 of 25 March 1986 laying down general rules for the production refund on certain sugar products used in the chemical industry, [4] as amended by Article 9 of Commission Regulation (EEC) No 1714/88 of 13 June 1988 [5] ('Regulation No 1010/86'), lays down rules relating to the grant of refunds to undertakings using sugar for the production of certain chemical products, including products covered by Chapter 30 of the Common

3 — 1 mcg corresponds to 1/1000 mg, consequently 50 mcg are the equivalent of 0.05 mg.

4 — OJ 1986 L 94, p. 9.

5 — OJ 1988 L 152, p. 23.

Customs Tariff relating to 'pharmaceutical products'.

The proceedings pending before the national court and the questions submitted for a preliminary ruling

6. Over the period from October 1989 to February 1991 the limited company Laboratoires de Thérapeutique Moderne ('LTM') received FF 410 347.56 in production refunds under Regulation No 1010/86, by declaring Alvityl 50 tablets and Strongenol 20 ampoules as pharmaceutical products.

7. However, the Fonds d'Intervention et de Régularisation du Marché du Sucre, which administers the aid scheme in France, refused to recognize them as pharmaceutical products within the meaning of Chapter 30 of the Common Customs Tariff and classified them instead as products covered by Chapter 21 ('miscellaneous edible preparations'). It demanded repayment of the refunds paid and also claimed penalties. LTM instituted proceedings against these claims before the Tribunal Administratif (Administrative Court), Paris.

8. At the material time, the composition of an Alvityl 50 tablet was as follows:

— vitamin A	6 250 IU
— vitamin B1	2.5 mg
— vitamin B2	2.5 mg
— vitamin B5	2.5 mg
— vitamin B6	0.75 mg
— vitamin B8	0.025 mg
— vitamin B9	0.0625 mg
— vitamin B12	0.0015 mg
— vitamin C	37.5 mg
— vitamin D3	500 IU
— vitamin E	5 mg
— vitamin PP	12.5 mg
— sugar	550 mg
— cocoa	92.5 mg
— excipients, flavourings, coating	

The content of vitamins A and D3 was subsequently reduced and is at present 1 500 IU and 150 IU respectively.

Alvityl was accompanied by the following information: 'this preparation is recommended for the prevention or correction of vitamin deficiencies due to an inadequate or unbalanced diet'.

In the course of the proceedings LTM referred to an expert report of 17 August 1990 by Dr Annie Rousseau, of LTM's clinical research and development department. This report concluded as follows:

'ALVITYL is indicated in certain deficiency conditions:

— restrictive or unbalanced diet regimes (low-calorie diets, strict vegetarian diets, etc.)

— chronic alcoholism

— long-term digestive disorders (malabsorption)

— for pregnant women and nursing mothers

— for individuals taking part in competitive sports

— for elderly persons.

ALVITYL is used in non-deficiency subjects in the symptomatic treatment of general debility.

NB: This product is not suitable for the treatment of a specific vitamin deficiency.'

9. At the material time, one 10 ml ampoule of Strongenol 20 had the following composition:

— iron	75 mg
— amino acids	800 mg
— sodium	2 mg
— copper	0.2 mg
— iodine	10 mg
— sugar	3.3 g
— glycerine	2 g
— orange extract	4 ml
— citric acid	pH 4.4

The addition of iodine was subsequently omitted.

Strongenol was accompanied by the following information concerning use:

'General debility or a reduction in physical or mental efficiency, convalescence, overwork, poor appetite, loss of weight, ageing'.

10. The Tribunal Administratif, Paris, stayed the proceedings and referred to the Court a question in the following terms:

'In order to resolve this dispute it is necessary to ascertain whether, having regard to their composition, presentation and purpose, the products "Alvityl 50 Dragées" and "Strongenol 20 Ampoules" fall within the scope of ... Council Regulation No 1010/86 of 25 March 1986 ...'.

Procedure before the Court

11. LTM contends that Alvityl and Strongenol are pharmaceutical products inasmuch as the French authorities issued a marketing authorization for both of them. Both are put up as pharmaceutical products as regards form and packaging. They both contain active substances and have a therapeutic purpose and, in any case, they have an appreciable effect on the body. They are pharmaceutical products with preventive and curative properties, taken in order to restore, correct or modify organic functions and they can be purchased only from pharmacists. Alvityl contains 50 to 150% of the recommended daily intake of most vitamins, serves to prevent or treat multi-vitamin deficiencies and is usually bought by patients on a doctor's prescription. Strongenol contains mineral salts, including iodine, and serves to treat all kinds of debility. Because of its iodine content, it may be taken only on a doctor's prescription.

12. The French Government has lodged observations in support of LTM and takes the view that Alvityl 50 is a vitamin product recommended for preventing or treating vitamin deficiencies. A lack of vitamin A may give rise to serious health problems. However, if taken in excess, it has toxic effects. That is why a doctor's prescription has, since 1992, been required in France for products containing concentrations of vitamin A over 5 000 IU. A deficiency of vitamins B1, B6, B9 and B12 and of vitamin E may also lead to significant health disorders. The vitamin content of Alvityl is so high that it can be used only for therapeutic or prophylactic purposes. Alvityl has effects on specific body functions and must therefore be regarded as a pharmaceutical product.

Strongenol 20 was prescribed to overcome iodine deficiency. Its iodine content indicates the product's therapeutic and prophylactic properties. Serious health problems may arise from both a deficiency and an excess of iodine. Strongenol 20 must be regarded as a pharmaceutical product by virtue of its iodine content.

13. The Commission contends that as the body requires a sufficient daily intake of vitamins, multi-vitamin tablets such as Alvityl should be regarded as a necessary part of the diet rather than as a pharmaceutical product. This is confirmed by the explanatory leaflet for Alvityl. The regular taking of products such as Alvityl has become a very widespread habit and they are consumed in order to maintain good health.

Strongenol cannot be regarded as a pharmaceutical product either. Very small quantities of metals (iron and copper), iodine and sodium serve, like vitamins and amino acids, to maintain good health and are not therefore intended for preventing or treating illnesses. This argument is supported by the explanatory leaflet for Strongenol.

General observations

14. It should be noted that Regulation No 1010/86 authorizes production refunds on sugar used for the products listed in the annex to the regulation. The annex refers to Chapter 30, 'Pharmaceutical products', of the Common Customs Tariff, but not Chapter 21, 'Miscellaneous edible preparations'. Therefore if products are in law covered by Chapter 21, they do not fall within the ambit of the regulation. Only if products are covered by Chapter 30 will they fall within the ambit of the regulation and it is only on this hypothesis that there will be a legal basis for granting the production refund. Consequently the issue in the case before the national court is whether the products are covered by Chapter 30 of the Common Customs Tariff and the question referred must therefore be construed as requesting interpretation of that chapter.

15. The Court has consistently held that, in the interests of legal certainty and ease of verification, the decisive criterion for the tariff classification of goods is in general to be sought in their objective characteristics and properties as defined in the wording of the relevant heading of the Common Customs Tariff and of the notes to the sections or chapters. It is also clear from the Court's case-law that, when construing the Common Customs Tariff, the notes which head the chapters of the Common Customs Tariff and the Explanatory Notes to the Nomenclature

of the Customs Cooperation Council are important means for ensuring the uniform application of the Tariff throughout the Community and as such may be regarded as useful aids to its interpretation: see the judgments in Case C-459/93 [6] and Joined Cases C-106/94 and C-139/94. [7]

16. With regard to the Customs Tariff, it is not necessary to examine the considerations on the basis of which a given product is classified as a pharmaceutical product under Community legislation or that of the Member States relating to pharmaceutical products. This is also clear from the general observations on Chapter 30 contained in the explanatory notes to the Common Customs Tariff, which state that 'The description of a product as a medicament in Community legislation ... or in the national legislation of the Member States, or in any pharmacopoeia, is not the deciding factor in so far as its classification in this chapter is concerned'.

The concept of 'pharmaceutical product' in the Common Customs Tariff therefore differs from that defined in Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products. [8] That directive was designed to eliminate — at least in part — obstacles to trade in proprietary medicinal products within the Community whilst at the same time attaining the essential objective of safeguarding public health. [9] Directive 65/65 thus permits a relatively wide range of products to come within the system of controls laid down by the legislation on pharmaceutical products in order to encourage trade and at the same time to protect public health. In view of the objective of consumer protection, therefore, the Court has broadly construed the first definition of the term 'medicinal product', taking the presentation of the product as its starting point. [10]

The fact that Alvityl and Strongenol have been marketed with the authorization of the French authorities and are therefore deemed by French law to be pharmaceutical products does not *ipso facto* mean that they must also be classified as pharmaceutical products under the Common Customs Tariff.

17. With regard to the concentration of certain substances in relation to the question whether vitamin preparations are pharmaceutical products, the Court made the

6 — *Hauptzollamt Hamburg-St Annen* v *Thyssen Haniel Logistic* [1995] ECR I-1381.

7 — *Colin and Dupré* [1995] ECR I-4759.

8 — OJ, English Special Edition 1965-1966, p. 20.

9 — See the judgment in Case 227/82 *Van Bennekom* [1983] ECR 3883.

10 — See the *Van Bennekom* judgment, cited in footnote 9, paragraph 17, Case C-112/89 *Upjohn* [1991] ECR I-1703, paragraph 16, and Case C-219/91 *Ter Voort* [1992] ECR I-5485, paragraph 16.

following observations in the *Van Bennekom* judgment:

'It is, however, apparent from the file and from the observations submitted to the Court, taken as a whole, that it is impossible in the present state of scientific knowledge to state whether the criterion of concentration alone is always sufficient in order to be able to determine whether a vitamin preparation constitutes a medicinal product; still less therefore is it possible to specify the level of concentration above which such a vitamin preparation would fall within the Community definition of a medicinal product.' [11] (paragraph 28).

18. For the purpose of the tariff classification of a product as a pharmaceutical product, it must be assumed that the decisive criterion is whether the product has a therapeutic or prophylactic application. The wording of heading No 30.04 of the Common Customs Tariff and the explanatory notes thereon are very clear on this point. The Court adopted the same approach in its judgment in Case C-177/91, [12] in which it found that 'hawthorn drops' should be classified under heading No 30.04 because that product had clearly defined therapeutic and, above all, prophylactic characteristics, the effect of which was concentrated on precise functions of the human organism, namely the cardiac, circulatory and neuro-vegetative functions.

11 — The case concerned the concept of 'medicinal product' in Council Directive 65/65/EEC.

12 — *Bioforce* [1993] ECR I-45, in particular paragraph 13.

Observations concerning Alvityl in particular

19. With regard to the tariff classification of Alvityl, some guidance is given by Regulation No 210/85, which provides that multivitamin and mineral pills with a specified composition must be classified as food preparations. The fifth recital in the preamble to this regulation states that these products have the characteristics of a food supplement containing vitamins and mineral salts and intended to keep the body in good health and that they should therefore be regarded as food preparations. The vitamin and mineral salt content indicated in Regulation No 210/85 corresponds in large measure to the recommendations of the Scientific Committee for Foodstuffs. [13]

20. The composition of Alvityl corresponds, so far as certain vitamins are concerned, to the figures given in Regulation No 210/85 and mentioned in the recommendations of the Scientific Committee. This fact supports the argument that Alvityl is in principle a food product in the same way as the pills referred to in Regulation No 210/85.

13 — Reports of the Scientific Committee for Foodstuffs (Series 31). Food and Energy Supplements in the European Community (report delivered on 11 December 1992). The values indicated relate to adults, men and women respectively. The Scientific Committee described these values as 'reference intakes for the population'. This term means the intake which is sufficient for practically everyone in good health in a given group.

21. So far as certain other vitamins are concerned, Alvityl contains quantities smaller than those mentioned in the regulation and recommended by the Scientific Committee. The fact that Alvityl contains some substances in a smaller proportion than in the case of the pills referred to in Regulation No 210/85 cannot, however, lead to the conclusion that Alvityl is a pharmaceutical product, but merely offers further support for the initial presumption that it must be regarded as a food preparation.

22. The question, therefore, is whether this initial presumption may be altered by reason of the fact that Alvityl has a relatively higher content of certain other vitamins than that indicated in Regulation No 210/85 and in the recommendations of the Scientific Committee. The table below shows the vitamins and minerals which appear in a higher concentration in Alvityl than in the product referred to in Regulation No 210/85:

	Alvityl	Regulation No 210/85	Committee Scientific
Vitamin A (IU)	6 250	2 000	2 000–2 330
Vitamin B1 (mg)	2.5	1.1	0.9–1.1
Vitamin B2 (mg)	2.5	1.2	1.3–1.6
Vitamin B9 (mg)	0.0625	0.05	0.2
Vitamin D (IU)	500	200	400

23. As the table shows, Alvityl has a vitamin A content approximately three times that of the pills referred to in Regulation No 210/85 and recommended by the Scientific Committee. Moreover, Alvityl tablets contain more vitamin D than the pills referred to in the regulation. The higher content of these vitamins is noteworthy in that both vitamins A and D can be taken in excessive quantities and this can have a detrimental effect on health. [14] On the other hand, this does not appear to be the case with regard to vitamins B1, B2 and B9, which are also contained in Alvityl in greater proportions than in the pills referred to in Regulation No 210/85.

14 — According to information supplied after the material time in the present case, the content of vitamins A and D in Alvityl has been reduced to 1 500 and 150 IU respectively to avoid the risk of hyper-vitaminosis (overdose).

24. In my opinion, the abovementioned basic presumption that Alvityl is to be treated as a food preparation of the kind referred to in Regulation No 210/85 must be upheld and it cannot be deemed to be a pharmaceutical product merely because it has a higher content of vitamins A, B1, B2 and D than the pills covered by Regulation No 210/85. [15] In particular, with regard to the higher vitamin A content, it should be observed that a number of ordinary foods (food preparations) also have a high content of vitamin A or provitamin A, which the human body can convert into vitamin A. As a comparison to the vitamin A content of Alvityl (6 250 IU), 100 g of calf liver contain 16 670 IU of vitamin A, and 100 g of carrots contain up to 5 550 IU of vitamin A (in the form of beta-carotene, which is a provitamin). [16]

25. A comparison between the composition of Alvityl and that of the pills mentioned in Regulation No 210/85 is therefore decisively in favour of the argument that Alvityl is a food, in the same way as the pills referred to in that regulation.

26. As appears from the abovementioned report by Dr Rousseau, Alvityl is also used in the treatment of certain deficiencies, including those connected with an unbalanced diet, and in the treatment of symptoms of general debility in subjects not suffering from a deficiency. On the other hand, Alvityl is not suitable for treating a specific vitamin deficiency.

27. Alvityl is therefore not intended to be used in the prevention or treatment of deficiencies of specific vitamins. Nor is it appropriate to be taken in order to obtain a high dosage of a specific vitamin as at the same time it entails the absorption of the other vitamins which are in the product and some of which may be taken in overdose. For example, to treat night blindness resulting from a deficiency of vitamin A, 30 000 IU or 50 000 IU of vitamin A are taken daily for a certain period. If six or eight Alvityl tables are taken instead each day for the same period, however, this will give rise to an overdose of vitamin D.

Alvityl is thus not intended for specific prophylactic or therapeutic use, as required by the *Bioforce* judgment cited above, and is in any case not suitable for that purpose.

28. Consequently Alvityl cannot be classified under Chapter 30 of the Common Customs Tariff dealing with pharmaceutical products, but must be regarded as a food preparation within the meaning of Chapter 21.

15 — On this point, see the *Van Bennekom* judgment, cited above in footnote 9.

16 — Source: *Tableau des Calories*, Anne Noel, Ed. S. A. E. P., Ingersheim, 1988.

Observations concerning Strongenol in particular

29. Strongenol contains no vitamins and only some of the numerous minerals which the body requires. The vitamins and most of the minerals in the tablets indicated as being food preparations for the purposes of Regulation No 210/85 are therefore not present at all in Strongenol, which also has only a low copper content. In principle, therefore, Strongenol cannot be considered a pharmaceutical product either.

30. In addition to the copper just mentioned, Strongenol also contains sodium, iron and iodine. Sodium is not listed in the pills referred to in Regulation No 210/85. By analogy with Alvityl and the proportions of certain vitamins it contains, Strongenol also has a higher iron and iodine content than the food preparations referred to in Regulation No 210/85 and than that recommended by the Scientific Committee, namely:

	Strongenol	Regulation No 210/85	Committee Scientific
Iron (mg)	75	10	9-20
Iodine (mg)	10	0.075	0.13

31. In my opinion, however, Strongenol cannot be considered a pharmaceutical product simply because it contains sodium and has a higher iron and iodine content than the pills indicated as food preparations under Regulation No 210/85 and than that recommended by the Scientific Committee. [17]

32. The information in the leaflet accompanying Strongenol indicated its use in cases of debility, reduced physical and mental efficiency, convalescence, overwork, poor appetite, loss of weight and ageing. These are widely differing conditions, defined in a very general manner, and are not in themselves illnesses or disorders, but merely more or less diffuse states of weakness. Strongenol was likewise not indicated as being applicable in the prevention or treatment of any disease or ailment, as required by the Explanatory

17 — At some time after the material period in this case, LTM eliminated iodine altogether from the composition of the product.

Notes relating to heading No 30.04 of the Common Customs Tariff and, furthermore, this product had no specific therapeutic or prophylactic effect either, as required by the *Bioforce* judgment.

33. For these reasons Strongenol cannot be classified for tariff purposes under heading No 30.04 or any other heading of Chapter 30.

Conclusion

34. In view of the foregoing, I propose that the Court give the following reply to the question submitted for a preliminary ruling:

The Common Customs Tariff must be interpreted as meaning that the term 'pharmaceutical products' used in Chapter 30 does not include products having the composition of the products which are the subject of this case.