OPINION OF ADVOCATE GENERAL STIX-HACKL

delivered on 2 October 2001 [1]

I — Introductory remarks

1. This case concerns the classification for customs tariff purposes of immunoglobulin concentrates from dried, defatted and decaseinated colostrum. The referring court seeks to ascertain whether such products are regarded as pharmaceutical products within the meaning of the Common Customs Tariff.

II — Legal framework

2. In the Community, goods are subject to classification for customs tariff and statistical purposes on the basis of the Combined Nomenclature (hereinafter 'CN') which is based on the international Harmonised System [2] (hereinafter 'HS'). The CN is set out in Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff. [3] The version applying to the period at issue in this case is established in Commission Regulation (EC) No 2086/97 of 4 November 1997 amending Annex I to Council Regulation (EEC) No 2658/87. [4]

3. Extracts from *Annex I to the CN* in the version relevant to the main proceedings read as follows:

'*CHAPTER 4*

DAIRY PRODUCE; BIRDS' EGGS;...

1 — Original language: German.

2 — Harmonised Commodity Description and Coding System established on the basis of the International Convention of 14 June 1983 which was approved by the Community by Council Decision 87/369/EEC of 7 April 1987 concerning the conclusion of the International Convention on the Harmonised Commodity Description and Coding System and of the Protocol of Amendment thereto (OJ 1987 L 198, p. 1).

3 — OJ 1987 L 256, p. 1.

4 — OJ 1997 L 312, p. 1.

Notes	
...	
4. This chapter does not cover:	
...	
(b) ... globulins (heading No 3504).	
...	
0404	Whey,... products consisting of natural milk constituents,...
...	
0408	Birds' eggs... and egg yolks,...
	— Egg yolks:
0408 11	— — Dried:
0408 11 20	— — —Unfit for human consumption
...	

CHAPTER 30

PHARMACEUTICAL PRODUCTS

...	
3001	Glands...
...	
3004	Medicaments...
...	

CHAPTER 35

ALBUMINOIDAL SUBSTANCES;...

...	
...	
3504 00 00	Peptones and their derivatives; other protein substances and their derivatives, not elsewhere specified or included;...
...	

...'.

4. Extracts from the *Explanatory Notes on the Harmonised Commodity Description and Coding System* published by the Customs Cooperation Council (hereinafter 'Explanatory Notes on the HS') read:

'04.04 — WHEY,...

...

The heading does not cover:

...

(e) ... globulins (heading 35.04).

...

30.01 — ... EXTRACTS OF GLANDS... OR OF THEIR SECRETIONS FOR ORGANO-THERAPEUTIC USES;...

...

The heading excludes:

...

(f) Globulins and globulin fractions (other than those of blood or serum) not prepared for therapeutic or prophylactic use (heading 35.04).

...'.

III — Facts and main proceedings

5. According to the referring court, the plaintiff in the main proceedings, Biochem Zusatzstoffe Handels- und Produktions GmbH (hereinafter 'Biochem'), applied to the Oberfinanzdirection Köln (Regional Finance Office, Cologne) for the issue of two binding tariff informations. Biochem was seeking classification of products consisting in a white powder, standardised by means of lactose, containing 15% or 30% of immunoglobulin concentrate, based on dried, defatted and decaseinated colostrum. It was seeking classification of the products as gland secretions for organo-therapeutic uses in heading No 3001 CN.

6. The Oberfinanzdirektion Köln passed the applications to the Oberfinanzdirektion Nürnberg (the defendant in the main proceedings, hereinafter 'the OFD') which is responsible under German law for products consisting of natural milk constituents. The OFD notified Biochem by the binding tariff

informations of 31 July 1998 that it classified the goods as modified whey in powder form, not containing added sugar or other sweetening matter, of a protein content exceeding 15% in subheading 0404 10 14 CN or 0404 10 12 CN respectively. Biochem brought an action before the referring court against the decision of 26 January 1999 rejecting its objection.

7. In the proceedings before the national court, Biochem essentially relied on the use and effect of the products which it described, according to the referring court, as follows:

'Immunoglobulins are antibodies which serve [5] the passive immunisation of new-born calves. Although the necessary dose of immunoglobulin is present in the mother's colostrum on the birth of a calf, new-born calves would inevitably die if they did not receive this colostrum with a corresponding proportion of immunoglobulins. The immunoglobulins in the colostrum create local immunisation protection in the alimentary tract and thus prevent digestive problems. The purpose of using the present products made from colostrum with an addition of immunoglobulins is, for example, to stop chains of infection through the mother's milk or to replace the mother cow. The products are used only on the first day of the new-born animal's life.... The product is used both for therapeutic and prophylactic purposes. As the animals would die without direct treatment with this product, there is a medical indication for direct treatment of a particular illness.'

8. Biochem argued that although the products were based on a form of whey (colostrum), the decisive factor for classifying the products was, however, the immunoglobulin content in a concentration of 15% or 30%. As a result, there was no question of classification in heading No 0404 CN. The products were, on the contrary, to be classified as secretions from glands for organo-therapeutic uses in heading No 3001 CN.

9. As grounds for rejecting the plaintiff's legal view, the OFD submitted that the lack of immune defence in new-born calves was natural and therefore did not constitute an illness. The products therefore were not pharmaceutical products within the meaning of Chapter 30 CN; regarded as milk, they were covered by Chapter 4 CN. Although milk was formed by the animal milk gland, it was, for customs tariff purposes, more specifically covered by Chapter 4 CN.

5 — Footnote only relevant in the German version.

10. The order for reference made by the national court on 19 April 2000 contains the following question for a preliminary ruling:

'Is the combined nomenclature in the version of Annex I to Regulation (EC) No 2086/97 (OJ 1997 L 312) of 4 November 1997 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff to be interpreted as meaning that immunoglobulin concentrates from dried, defatted and decaseinated colostrum, standardised by means of lactose, are to be classified as pharmaceutical products in Chapter 30?'

IV — The question referred for a preliminary ruling

11. These proceedings relate to the classification for customs tariff purposes of two products involving the same substance and distinguished only by their respective immunoglobulin content (15% or 30%). Since the percentage proportion is irrelevant to the question whether they are covered for customs tariff purposes by Chapter 30 CN or Chapter 4 CN, the term 'immunoglobulin concentrates' is used hereinafter to refer to the two products.

Arguments of the parties

12. Biochem and the Commission take the view that the immunoglobulin concentrates are pharmaceutical products within the meaning of Chapter 30 CN. They essentially take the purpose of the products as the basis for that argument. That purpose is solely to provide prophylactic immunisation for new-born calves and, in certain cases, immunisation which serves to prevent the spread of infection from the mother cow to the new-born calf. In their view, the immunoglobulins in addition created local immunisation protection in the alimentary tract and thus prevented digestive problems. The immunising effect was apparent from the particularly high percentage content of immunoglobulin. The fact that colostrum present in cows formed the basis for preparing the immunoglobulins in the concentrates was of secondary importance as regards tariff classification, as was the fact that lactose was used as a water-soluble vehicle to standardise the products. The nutritional value of the immunoglobulin concentrates for new-born calves was so low in fact that the immunoglobulin concentrates could not be used for nutritional purposes.

13. In support of its argument, Biochem relies on Explanatory Note (f) [6] on heading 30.01 HS. According to that note, globulins

6 — Reference was made in the written observations to 'Explanatory Note 17.0 on heading 3001 HS'. However, the text cited is clearly set out in Explanatory Note (f) on heading 30.01 HS.

not prepared for therapeutic or prophylactic use are excluded from heading 30.01 HS, and thus conversely it must be assumed that globulins such as the immunoglobulin concentrates at issue which indeed are used for prophylactic or therapeutic purposes are to be classified in heading No 3001 CN.

14. The Commission first makes a general reference to the General Rules for the Interpretation of the Combined Nomenclature and to the settled case-law of the Court that classification for customs purposes within the Combined Nomenclature must in general be effected on the basis of their objective characteristics and properties and the Explanatory Notes on the HS constitute an important aid.[7] Furthermore, it explicitly relies on the settled case-law of the Court concerning the distinction made between pharmaceutical products in heading No 3004 CN (medicaments) and headings other than those included in Chapter 30 CN. The Court's distinction turned on whether products have clearly defined therapeutic or prophylactic characteristics, the effect of which is concentrated on precise functions of the organism.[8] The immunoglobulin concentrates at issue were prepared for such therapeutic and prophylactic uses since they serve to prevent diseases occurring where there is a lack of immune defence or are administered to treat diseases which have already occurred.

15. The Commission also considers that the immunoglobulin concentrates cannot be classified in heading No 0404 CN (whey or products consisting of natural milk constituents). It has submitted that colostrum present in cows, which forms the basis of the immunoglobulins, is neither whey in the strict sense nor milk. By virtue of its particularly high concentration of immunoglobulins and its very low nutritional content, colostrum is not a food; it is an immunisation preparation.

16. The OFD maintains the view it put forward in the proceedings before the national court, that the immunoglobulin concentrates should be classified for customs tariff purposes as modified whey. It considers that the immunoglobulin concentrates should be classified in heading No 0404 CN because they constitute modified whey in powder form which is covered word for word by subheading 0404 10 CN (whey and modified whey). Thus, classification in a different chapter of the CN was impossible. Even the condition 'not elsewhere specified or included' contained in heading No 0404 CN was immaterial in that regard because it referred to the second part of heading No 0404 CN (products consisting of natural milk constituents) rather than to the first part (whey).

Assessment

17. The parties in the main proceedings essentially disagree on whether the prod-

7 — Case C-201/96 *LTM* v *FIRS* [1997] ECR I-6147.

8 — Case C-177/91 *Bioforce* v *Oberfinanzdirektion München* [1993] ECR I-45; *LTM*, cited in footnote 7; Case C-270/96 *Sarget* v *FIRS* [1998] ECR I-1121.

ucts at issue in this case can be classified in one of the headings of Chapter 4 CN (as dairy produce) or in one of the headings of Chapter 30 CN (as secretions from glands for organo-therapeutic uses).

18. The Court has consistently held that, in the interests of legal certainty and ease of verification, the decisive criterion for the classification of goods for customs purposes is in general to be sought in their objective characteristics and properties as defined in the wording of the relevant heading of the CN. [9] The corresponding explanatory notes drawn up by the Customs Cooperation Council as regards the Harmonised Commodity Description and Coding System may be an important aid to the interpretation of the scope of the various tariff headings but do not have legally binding force. [10]

19. Therefore, the wording of the relevant tariff headings will be examined first below in connection with the relevant notes on the CN and the relevant explanatory notes on the HS. If, on such examination, it is found that classification is possible in several headings, other criteria must be taken into account in accordance with the case-law of the Court. [11]

— Classification in Chapter 4 CN

20. On the basis of Biochem's undisputed description of the immunoglobulin concentrates, there are criteria to support and reject classification by reason of wording in heading No 0404 CN (whey...; products consisting of natural milk constituents,...):

First, the fact that lactose is used as a water-soluble vehicle to improve the administrability of the concentrated immunoglobulins points to classification in that heading. However, according to the case-law of the Court, [12] such vehicles in themselves are irrelevant as regards tariff classification of the product as a whole, and therefore the sole fact that lactose is used cannot in this instance result in classification in Chapter 4 CN.

9 — Case C-459/93 *Thyssen Haniel Logistic* [1995] ECR I-1381 and Joined Cases C-106/94 and C-139/94 *Colin and Dupré* [1995] ECR I-4759.

10 — Case C-35/93 *Develop Dr. Eisbein* v *Hauptzollamt Stuttgart-West* [1994] ECR I-2655 and *Colin and Dupré*, cited in footnote 9.

11 — See point 35.

12 — See *Bioforce*, cited in footnote 8.

21. Furthermore, colostrum present in cows is the basis for the immunoglobulin which characterises the immunoglobulin concentrates. In its natural form, colostrum is the first 'mother's milk' that new-born calves usually receive from the mother cow.

22. However, doubts could arise as to whether immunoglobulin concentrates can be classified as 'milk' or 'whey' in a heading of Chapter 4 CN because the colostrum used in the preparation of immunoglobulin concentrates cannot in this case be used for nutritional purposes, as 'milk' or 'whey' usually can. On the contrary, colostrum is a substance which in itself predominantly consists of immunoglobulins and contains only a very small proportion of nutritional components. If the colostrum is then decaseinated and defatted, as it is in this case, the nutritional function becomes entirely insignificant.

23. In that respect, however, it remains unclear whether classification in the various headings of Chapter 4 CN may in any case depend on whether the products concerned serve to feed living beings or are at least suitable for consumption. The predominant argument against that consideration is that, in all its subheadings, for instance in subheading 0408 11 CN (Egg yolks, dried), heading No 0408 CN (Birds' eggs, not in shell, and egg yolks,...) contains a further subsection for products which are described as being 'unfit for human consumption' (e.g. 0408 11 20 CN).

24. For the time being, it can therefore be stated for the record that the immunoglobulin concentrates could in principle be covered by the wording of heading No 0404 CN by reason of the fact that they essentially consist of immunoglobulins from the colostrum of dairy cows (first 'mother's milk' for new-born calves).

— Classification in Chapter 30 CN

25. On the basis of Biochem's undisputed description of the immunoglobulin concentrates, there are also criteria to support and reject classification by reason of wording in heading No 3001 CN (extracts of glands... or of their secretions for organo-therapeutic uses...).

26. Colostrum present in cows is without a doubt a secretion produced from glands. Its purpose is organo-therapeutic since it serves the passive immunisation of new-born calves which do not have their own adequate, natural store of immunisation protection directly after their birth. Immunoglobulin concentrates are administered on the first day of the new-born animal's life as a preventive measure in case colostrum, the natural substance which contains immunoglobulin and compensates for such immunodeficiency, should not be available from the mother cow or in case infection should have to be prevented from spreading from the mother cow to the calf. Moreover, the immunoglobulins create local immunisation protection in the alimentary tract and generally prevent digestive problems in calves.

27. The OFD's counter-argument, that there could be no question of therapeutic or prophylactic use because the lack of personal passive immunisation in new-born calves was natural and therefore was not an illness, is in that respect unconvincing. Therapeutic or prophylactic effects by all means may be indicated even where there are innate deficiencies. The only relevant point is that failure to remedy the deficiency leads to physical problems or, as in this case, even to the animal's certain death. By creating local immunisation protection in the alimentary tract, the immunoglobulin concentrates ultimately provide preventive protection against digestive problems in calves, which indicates that there must be a further prophylactic use which is not aimed (only) at making up for an innate deficiency.

28. Consequently, it can be stated first of all that the immunoglobulin concentrates could be covered by the wording of heading No 3001 CN.

29. However, a different conclusion could be reached following consideration of the Notes on the CN and the Explanatory Notes on the HS.

30. According to Note 4(b) on Chapter 4 CN and Note (e) on heading 04.04 in the Explanatory Notes on the HS, globulins are to be classified in heading No 3504 CN. Taken in isolation, those notes would appear to suggest that all globulins, including immunoglobulins and by extension the immunoglobulin concentrates in question, are covered by heading No 3504 CN. This would, however, preclude classification for customs tariff purposes in one of the headings of Chapter 30 CN.

31. Note (f) on heading 30.01 in the Explanatory Notes on the HS on the other

hand points to classification in Chapter 30 of the CN, in heading No 3001 CN to be more precise. The wording of that note is more restrictive than that of Note 4(b) on Chapter 4 CN as regards the tariff classification of globulins. Note (f) on heading 30.01 in the Explanatory Notes on the HS states that only globulins *other than those of blood or serum* which are *not prepared for therapeutic or prophylactic use* are to be covered by heading 35.04 HS.

32. The characteristic substance of the immunoglobulin concentrates at issue in this case indeed is obtained from the colostrum of dairy cows, not therefore from (in this case, animal) blood or serum, [13] and thus the first criterion appears to be fulfilled. However, the immunoglobulin concentrates are, as stated above, prepared for prophylactic or therapeutic use, and thus the second criterion for classification in heading 35.04 HS is not fulfilled.

33. Consequently, it can be stated that the immunoglobulin concentrates could in principle be covered by the wording of Chapter 30 CN because they essentially consist of immunoglobulins from the colostrum of dairy cows.

— Distinction between Chapter 4 CN and Chapter 30 CN

34. If it is consequently to be established that the immunoglobulin concentrates at issue could, by virtue of their objective characteristics and properties, be covered both by the wording of a heading in Chapter 4 CN and by the wording of a heading in Chapter 30 CN, criteria other than those involving the wording of the relevant headings and involving the interpretation of the Explanatory Notes on the HS must be taken into account for the purpose of tariff classification.

35. The Court already had to address the issue of product classification for customs tariff purposes in previous judgments where, for instance, it was unclear whether the products should be classified as medicaments in heading No 3004 CN or else in other headings not included in Chapter 30 CN. In that regard, it essentially took the question whether the product concerned has a clearly defined therapeutic or prophylactic characteristic, the effect of which

13 — If they [the immunoglobulins] had been obtained from animal blood or serum, they would definitely be classified in subheading 3002 10 91 CN (blood globulins); compare with the classification of monoclonal antibodies for customs tariff purposes in Case C-191/91 *Abbott* v *Oberfinanzdirektion Köln* [1993] ECR I-867.

is concentrated on precise functions of the organism,[14] to be the basic criterion for classification in heading No 3004 CN (medicaments...).

36. Although within Chapter 30 CN immunoglobulin concentrates cannot be regarded as medicaments within the meaning of heading No 3004 CN on account of the precise description of origin contained in heading No 3001 CN (secretion from glands), the criteria developed in the case-law mentioned in the preceding paragraph for distinguishing between medicaments and other headings not included in Chapter 30 CN can still be applied in a more general manner.

37. All of the headings in Chapter 30 CN are, after all, distinguished from the headings in other chapters of the CN, including from the headings in Chapter 4 CN, by the fact that they *serve a specific purpose.* If and in so far as it is possible to classify goods for customs tariff purposes in accordance with the wording of the relevant headings both in a heading which covers products not having a clearly specified use and in a heading of Chapter 30 CN, that is to say where there is a specified (in this case, therapeutic or prophylactic) use, then, in cases of doubt, the therapeutic or prophylactic effect must be the decisive factor where it constitutes the main use of the product and it is focused against a particular illness or a particular organic disease or a particular deficiency.

38. Such are the circumstances in this case. Colostrum present in cows or at least the essential component of colostrum (immunoglobulin) is a characteristic feature of the immunoglobulin concentrates at issue. Immunoglobulin has a prophylactic and, where necessary, therapeutic effect as regards the passive immunisation of new-born calves. The effect is focused on prevention or treatment of a particular illness (new-born calves not yet having adequate immunisation protection of their own).

39. The immunoglobulin concentrates at issue thus fulfil the essential criteria which the Court laid down in the abovementioned case-law[15] in respect of classification for customs tariff purposes in one of the headings of Chapter 30 CN (pharmaceutical products).

14 — *Bioforce*, cited in footnote 8; *LTM*, cited in footnote 7; Case C-328/97 *Glob-Sped AG* v *Hauptzollamt Lörrach* [1998] ECR I-8357.

15 — Cited in footnote 14.

V — Conclusion

40. In the light of the foregoing considerations, I therefore propose that the Court answer the question referred by the national court as follows:

The combined nomenclature in the version of Regulation (EC) No 2086/97 (OJ 1997 L 312) of 4 November 1997 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff is to be interpreted as meaning that immunoglobulin concentrates from dried, defatted and decaseinated colostrum, standardised by means of lactose, are to be classified as pharmaceutical products in Chapter 30.