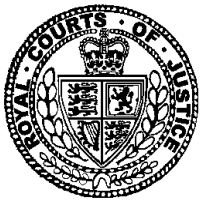

[2013] UKUT 0483 (TCC)
Case No: FTC/61/2012

UPPER TRIBUNAL (TAX AND CHANCERY CHAMBER)

Royal Courts of Justice
Rolls Building, Fetter Lane
London EC4A 1NL

Date: 27 September 2013

Before :

Mr Justice Roth

- -

Between :

THE COMMISSIONERS FOR HER MAJESTY'S REVENUE & CUSTOMS **Appellants**

- and -

SHS INTERNATIONAL LTD **Respondent**

- -
- -

Mr Vinesh Mandalia (instructed by **the General Counsel and Solicitor for HM Revenue & Customs**) for the **Appellants**
Mr Tim Brown (instructed by **Weightmans LLP**) for the **Respondent**

Hearing date: 20 May 2013

- -

APPROVED DECISION

Mr Justice Roth :

Introduction

1. This appeal, brought with permission granted by the First-Tier tribunal ("FTT"), raises a short but significant point as regards the interpretation of the Combined Nomenclature ("CN") set out by the European Union pursuant to Council Regulation No. 2658/87.

2. The respondent ("SHS") imports two different formulations of pre-mixes of amino acids, known as RM510 and RM630. RM510 is used by SHS in the production of its product range called "Maxamum" and RM630 is used in the production of its product range called "Neocate".

3. The issue in the case is whether RM510 and RM630 are properly to be classified as medicaments under heading 30.03 of the CN, as contended by SHS, or instead to be classified as food preparations under heading 21.06 as contended by the appellants ("HMRC"). If SHS is correct and they are to be classified under 30.03, the importation of these products is free of duty. If HMRC are correct, then the products are subject to duty at the rate of 12.8%, which is the basis upon which HMRC issued the post-clearance demand for duty that was challenged before the FTT.

4. The FTT upheld the contention of SHS. Its reasoning is contained in two documents since it accepted that its original decision issued on 16 February 2012 contained an error of law and did not give sufficient detail of its reasoning. It therefore issued a further decision notice by way of review of the first decision on 4 July 2012. It is common ground between the parties that the decision below is expressed in the combined effort of those two documents, the first to be read subject to the correction and elaboration found in the second.

The legislative regime

5. The legal framework is somewhat complex and I adopt the helpful summary provided by Laws J in *HM Customs & Excise v Cedar Health Ltd* (unreported) 21 May 1998, as quoted in *Unigreg Ltd v HMRC* [1998] EWHC Admin 725 at [4] by Moses J:

> "(1) The classifications contained in the Combined Nomenclature contained in Council Regulation 2658/87 are contained in that regulation's Annex 1.
>
> (2) The Annex, updated from time to time, contains general rules of interpretation which provide that classification shall be determined according to the terms of headings and any relevant section or chapter notes (Rule 1).
>
> (3) The various numbered headings are grouped under Chapters, the first two digits of each heading corresponding with the Chapter numbers. Thus Chapter 21 is headed: "Miscellaneous edible preparations" and 21.06: "Food preparations not elsewhere specified or included". Chapter 30 is headed: "Pharmaceutical products" and 30.04: "Medicaments

> (Excluding Goods of Heading 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 packagings for retail sale."
>
> (4) The Combined Nomenclature Explanatory Notes form part of the tariff and are legally binding.
>
> (5) Harmonised System Explanatory Notes ("HSEN"), relating to the harmonised system convention on which the common customs tariff was based, whilst not legally binding are important aids to interpretation.
>
> (6) There are provisions to ensure that products do not fall under more than one heading. Thus, by Note 1(f) of Chapter 21, products under 30.04 are not covered by Chapter 21. By Chapter 30, Note 1(a), Chapter 30 does not cover:
>
> > "(a) foods or beverages (such as dietetic, diabetic or fortified foods, food supplements tonic beverages and mineral waters) (Section IV).""

Moses J added that if a product would otherwise fall under two or more headings, it falls exclusively under the heading which is more specific.

6. That summary quotes heading 30.04. As mentioned above, the issue in this case concerns 30.03, which is headed as follows:

> "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 packagings for retail sale."

The only difference between 30.03 and 30.04, therefore, is as to whether or not the goods are in measured doses or packaged for retail sale.

7. In Case C-328/97 *Glob-Sped v Hauptzollamt Lörrach* [1998] ECR I-8371, the Court of Justice ("ECJ") stated at para 26, in a formulation that has been repeated many times since:

> "It is settled case-law that, in the interests of legal certainty and for 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. There are also explanatory notes drawn up as regards the CN, by the Commission and, as regards the Harmonised Commodity Description and Coding System, by the Customs Cooperation Council, which may be an important aid to the

> interpretation and scope of the various tariff headings but do not have legally binding force…."

8. The HSEN to 21.06 provides, at para (16) that Heading 21.06 covers:

> "Preparations, often referred to as *food supplements*, based on extracts from plants, fruit concentrates, honey, fructose, etc and containing added vitamins and sometimes minute quantities of iron compounds. These preparations are often put 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)"

This note is incorporated in the UK Tariff Classification: see para 21 of the FTT's second decision.

9. In the *Glob-Sped* case, the ECJ considered the application of the CN to two vitamin C preparations, one in the form of soluble tablets and the other of chewing tablets. The German customs authority had considered that the preparations were aimed primarily at compensating for a deficiency in vitamin C and were not specifically effective against certain illnesses, and that they were accordingly to be classified under 21.06. On a reference by the German court, the ECJ held that the preparations could not be regarded as simply a food supplement but fell to be classified under 30.04, stating in its judgment (at para 28):

> "… it is undisputed that the vitamin C content of the products in question is much greater than what is necessary or recommended for general dietary purposes. Furthermore, besides assisting the immune system of the human organism to resist infections in cases of, *inter alia*, asthenia or severe strain, such doses of vitamin C, which the human body is incapable of making for itself, are also recommended as treatment for allergic reactions and severe traumatisms, of the kind which may result from an injury or a surgical operation, or to combat deficiency-related illnesses, such as scurvy or Moeller-Barlow disease."

The facts

10. The hearing before the FTT extended over three days and it heard seven witnesses, including three independent experts. The essential facts, as set out in the decisions of the FTT, are simple and not in dispute.

11. Both the Maxamum and Neocate products are available on prescription only and used in the treatment of people with metabolic disorders.

12. Maxamum, incorporating the pre-mix RM501, is prescribed for adults and children over 8 years old who suffer from Phenylketonuria ("PKU"). PKU is an inherited metabolic disease for which there is no cure. It involves a deficiency of the enzyme, phenylalanine hydroxylase, as a result of which the body is unable to break down the

amino acid, phenylalanine ("PHE"). Failure properly to manage the condition causes high levels of PHE to accumulate in the blood, leading to a range of serious mental and physical conditions, including severe intellectual disability and epilepsy. RM510 comprises a mix of 19 l-amino acids, excluding PHE, as a protein substitute; and administration of Maxamum also has the pharmacological effect of assisting the release of PHE into the body tissue rather than the blood stream. Dr MacDonald, a consultant dietician at Birmingham Children's Hospital called as an expert witness by SHS, gave evidence of two case studies whereby treatment with Maxamum substantially increased the concentration and memory span of an 8 year old child and the concentration and executive functions of a 56 year old. She explained such treatment not only improved the patient's health and well-being but prevented the complaint from escalating.

13. RM501, as the active ingredient, comprises some 47% of the Maxamum product.

14. Neocate, containing the pre-mix RM630, is given to babies who suffer from a milk allergy and are intolerant to cow's milk. The allergy can cause vomiting, diarrhoea, breathing problems and skin problems. As with PKU, there is no cure for the allergy. Neocate omits the offending metabolite but contains other essential amino acid ingredients thereby meeting the nutritional needs of the infant and also serves to treat the underlying allergy symptoms. Dr Meyer, a paediatric teaching fellow at Imperial College London, gave as examples a baby who developed eczema at one month old and did not respond to standard treatment but after changing to Neocate he showed a marked improvement after 5 days and the eczema was totally cleared after 3 weeks; and of the use of Neocate as an effective temporary treatment for colic in breast-fed infants.

15. RM630, as the active amino acid ingredient, comprises about 15.5% of Neocate.

The appeal

16. HMRC's written application put forward six grounds of appeal, but grounds 2 and 4 fell away in the light of the FTT's further decision notice, and a challenge on *Edwards v Bairstow* grounds, that the decision was one which the FTT could not reasonably reach on the evidence, was not pursued in argument. It became clear that the effective challenge to the decision was advanced on two bases.

17. First, it was submitted that the FTT had in reality applied the wrong test. To satisfy 30.03, the imported product must, on the basis of its objective properties, be for therapeutic or prophylactic uses, whereas these pre-mixes neither cured nor prevented the relevant medical conditions. They were in reality used as food substitutes which avoided the intake of offending substances by patients with those medical conditions.

18. There is no definition of "therapeutic" in the notes to 30.03 or 30.04. However the note to 21.06 in the HSEN explaining that food supplements are generally included in that heading states that similar preparations "intended for the preparation or *treatment* of diseases or ailments are excluded" and fall within headings 30.03 or 30.04: para 8 above. And the FTT referred to the dictionary definition whereby "therapeutic" does not only mean "tending to the cure of disease" but also refers to "medical treatment": para 13 of the first decision.

19. I reject the submission advanced for HMRC that "treatment" in this context is restricted to mean treatment so as to cure. In the *Glob-Sped* judgment quoted above, the ECJ significantly referred to the vitamin C preparations being used for "treatment" of allergic reactions: they did not cure the underlying allergy. To make a distinction in the application of these categories of Chapter 30 as between products that cure a disease and products that control or suppress its symptoms seems to me in any event artificial. Of the many examples that could be given, insulin used in the treatment of diabetes demonstrates that a product that neither prevents nor cures an underlying medical condition is, on an objective characterisation, manifestly a medicament. Counsel for HMRC was unable to suggest where this product would come under the comprehensive CN if it was not a medicament within 30.03 or 30.04. Use for the purpose of treatment of a disease by control or prevention of the symptoms, in my judgment, falls within the concept of "therapeutic" as used in those numbered headings.

20. On that basis, the evidence as referred to above clearly shows that both Maxamum and Neocate have the effect of controlling and sometimes relieving altogether the effects of these particular metabolic diseases, by working on particular functions of the body. Moreover, it went somewhat further in Dr MacDonald's reference to treatment with Maxamum as preventing "an increase in the disease". It appears that this was because it has the effect of suppressing the release of PHE into the blood stream. Similarly, for Neocate, it may have the effect of clearing up eczema or, through temporary administration, colic, although it could not cure the underlying milk allergy.

21. It is common ground that the fact that these products are available only on prescription is not of particular relevance: see Case C-201/96 *LTM v FIRS* [1997] ECR I-6162. But I consider that the FTT was amply justified in concluding on the evidence that both Maxamum and Neocate are more than just food supplements and were medicaments within the meaning of the relevant classification.

22. Secondly, it was submitted that the FTT had failed to distinguish between the final products administered to patients, i.e. Maxamum and Neocate, and the pre-mixes RM510 and RM630. The objective characteristics which had to be determined for application of the CN were those of the pre-mixes not the final product.

23. I consider that there was force in this criticism as regards the original decision of 16 February 2012. However, on review in the second decision I find that the FTT paid appropriate attention to this point and addressed itself specifically to the pre-mixes: paras 27-29 of the second decision. It found that the pre-mixes "import that part of the formula which contains the medicinal amino-acids," and that the pre-mixes, as well as the final products, were properly classified as medicaments.

24. In Case C-177/91 *Bioforce I* [1993] ECR I-60, the ECJ considered whether hawthorn drops, comprising an extract of hawthorn with added alcohol that may be taken as a tonic for the heart, was a medicament within heading 30.04. The alcohol represented 45.9% by volume of the end product. Holding that the drops were not to be regarded as a food supplement but fell under heading 30.04, the ECJ observed (at para 11):

> "… the alcohol contained in the product, *however high the percentage may be*, does not change its nature. On the

> contrary, its function is to act as an adjuvant, a preservative and a vehicle for the active principles of the said product." [emphasis added]

A statement to similar effect was made in Case C-405/95 *Bioforce II* [1997] ECR I-2590, concerning the product "Echinaforce" which had an alcoholic strength of 65% by volume: see at para 17.

25. Although Mr Mandalia, for HMRC, referred to the fact that carbohydrate constituted 54% of Neocate, there was no evidence to suggest that it was this carbohydrate element which provided the treatment of the infant's medical condition. On the contrary, Mr Cowley of SHS explained:

> "… in the early months of [the infant's] life it is likely that SHS's nutritional product will entirely replace any other source of nutrition for the infant patient. Accordingly it is necessary that the product provides not only the correct amino acid profile to assist the treatment of the medical condition, but also that it provides the other nutritional elements that the infant requires, i.e. fat, carbohydrate, vitamins minerals and trace elements."

Accordingly, the carbohydrate element is incorporated as a true food substitute. It is the amino acid pre-mix that provides the treatment of the allergic condition and its effects.

26. Further, there is nothing in the heading of 30.03 which requires the product to be put to therapeutic or prophylactic use in isolation, as distinct from being the therapeutic or prophylactic ingredient in another product. Medicinal drops to be taken in water are no less a medicament because they are not consumed on their own. And as regards RM510, although Dr MacDonald recognised that it was not taken on its own but only incorporated in Maxamum, she said that if Maxamum was not available and there was no other product she would use RM510 on its own because of its metabolic effect.

27. Therefore I find that the fact that the pre-mixes constituted less than half of the final product (and in the case of Neocate much less than half) does not vitiate the FTT's conclusion that not only the final products but also the pre-mixes are to be classified as medicaments.

Conclusion

28. It follows that the appeal is dismissed.

MR JUSTICE ROTH

RELEASE DATE: 27 SEPTEMBER 2013