OPINION OF ADVOCATE GENERAL

WAHL

delivered on 2 June 2016 (1)

Case C?412/15

TMD Gesellschaft für transfusionsmedizinische Dienste mbH

v

Finanzamt Kassel II - Hofgeismar

(Request for a preliminary ruling from the Hessisches Finanzgericht (Finance Court, Hesse, Germany))

(Value added tax — Deductions — Article 132(1)(d) of the VAT Directive — ‘Blood’ — Supplies of blood plasma for manufacturing medicinal products)

1. The present proceedings raise, in essence, the following question: is the supply of blood plasma for the purpose of manufacturing medicinal products a transaction exempt from VAT?

2. To deal with this issue, the Court will, first, have to define ‘blood’ within the meaning of Article 132(1)(d) of the VAT Directive (2) and, second, examine whether a distinction should be made, under that provision, between plasma intended for therapeutic purposes and that intended for the manufacturing of medicinal products.

I – **Legal framework**

A – *EU law*

3. Article 132 of the VAT Directive provides:

‘1. Member States shall exempt the following transactions:

…

(b) hospital and medical care and closely related activities undertaken by bodies governed by public law or, under social conditions comparable with those applicable to bodies governed by public law, by hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature;

(c) the provision of medical care in the exercise of the medical and paramedical professions as defined by the Member State concerned;

(d) the supply of human organs, blood and milk;

(e) the supply of services by dental technicians in their professional capacity and the supply of dental prostheses by dentists and dental technicians;

…’

B – *National law*

4. Paragraph 4 of the Umsatzsteuergesetz (Law on turnover tax, ‘the UStG’), provides:

‘The following transactions covered by Paragraph 1(1)(1) shall be exempt:

…

1(b): intra-Community supplies of goods ….

…

17(a): supplies of human organs, blood and milk.’

5. Paragraph 15 of the UStG provides:

‘(1) A trader may deduct the following amounts of input tax:

1. tax statutorily payable on goods and services provided to his business by another trader. …

(2) There shall be no deduction of input tax in respect of the supply, importation or intra-Community acquisition of goods, or in respect of supplies of services, which the trader uses for the purposes of the following transactions:

1. exempt transactions;

…

(3) The exclusion of the input tax deduction referred to in subparagraph 2 shall not apply where the transactions:

1. in the cases provided for in point 1 of the first sentence of subparagraph 2

(a) are exempt in accordance with Paragraph 4(1) to (7). …’

6. Section 4.17.1 of the Umsatzsteuer-Anwendungserlass (Decree on the application of turnover tax, ‘the UStAE’) provides:

‘(1) Human blood includes the following products: fresh blood, whole blood, serum and plasma, heparinised blood and cellular blood components.

(2) Preparations produced from mixtures of human plasma are not covered by the exemption. These include in particular: factor preparations, human albumin, fibrinogen, immunoglobulin.’

II – **Facts, procedure and the questions referred**

7. TMD Gesellschaft für transfusionsmedizinische Dienste mbH (‘TMD’) operates a blood donor centre. In the course of its activity, it supplied blood plasma for the purpose of

manufacturing medicinal products to X AG, a company established in Switzerland, which collected the plasma from TMD and transported it to its production facilities elsewhere in the European Union.

8. In its turnover tax return submitted to the Finanzamt Kassel II ? Hofgeismar ('Finanzamt') for 2008, TMD deducted the input tax relating to these supplies. The Finanzamt refused the deduction of input tax however on the ground that the supplies of blood plasma to another part of the Union were exempt from tax, both as intra-EU supplies under Paragraph 4(1)(b) of the UStG and as supplies of blood under Paragraph 4(17)(a) of the UStG. The Finanzamt thus concluded that the deduction of input tax was precluded by Paragraph 15(2) of the UStG.

9. In its returns for 2009 and 2010, which the Finanzamt accepted, TMD did not deduct any input tax.

10. On 7 December 2012, TMD requested amendment of the turnover tax assessments for the years 2008 to 2010, which had been issued subject to the possibility of review. It asked for the input tax relating to the supply of plasma to be recognised. In support of its request, it contended that the intra-EU supplies of blood plasma to which the input tax amounts now claimed related were not exempt under Paragraph 4(17)(a) of the UStG as they involved the supply of source plasma to pharmaceutical companies for fractionation and subsequent manufacture of medicinal products. Consequently, the tax exemption was founded on Paragraph 4(1)(b) of the UStG only and the deduction of input tax therefore had to be allowed.

11. The Finanzamt refused the requests for amendment by order of 7 May 2013. TMD thus brought an action before the referring court with the aim of requiring the Finanzamt to amend the tax assessments.

12. In support of its action, TMD contended that the supply of blood plasma destined for the manufacturing of medicinal products does not constitute a supply of blood within the meaning of Paragraph 4(17)(a) of the UStG, or Article 132(1)(d) of the VAT Directive. The Finanzamt, for its part, opposes the arguments put forward by TMD and contends that its interpretation of the law corresponds also to the letter of Section 4.17.1 of the UStAE.

13. In those circumstances, the referring court decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is Article 132(1)(d) of Directive 2006/112/EC to be interpreted as meaning that the supply of human blood also encompasses the supply of blood plasma obtained from human blood?

(2) If Question 1 is answered in the affirmative: does this also apply to blood plasma that is not intended to be used directly for therapeutic purposes, but exclusively for manufacturing medicinal products?

(3) If Question 2 is answered in the negative: is classification as blood solely dependent on the intended purpose of the blood plasma, or also on the uses to which the blood plasma may theoretically be put?'

14. Written observations in the present proceedings have been submitted by TMD, the German and Hungarian Governments and the Commission. TMD, the German Government and the Commission also presented oral argument at the hearing on 28 April 2016.

III – **Consideration of the questions referred**

A – *Question 1*

15. By its first question, the referring court asks whether the term ‘blood’ in Article 132(1)(d) of the VAT Directive encompasses blood plasma obtained from human blood.

16. TMD takes the view that the question should be answered in the negative whereas the German and Hungarian Governments and the Commission are of the opinion that it should be answered positively.

17. At the outset, I would call to mind that, according to settled case-law, the purpose of the exemptions provided for in Article 132(1) of the VAT Directive is to facilitate access to certain services and the supply of certain goods by avoiding the increased costs that would result if they were subject to VAT. Those exemptions constitute independent concepts of EU law the purpose of which is to avoid divergences in the application of the VAT system from one Member State to another. (3)

18. The exemptions in Article 132(1) of the VAT Directive are to be interpreted strictly since they constitute a departure from the general principle that VAT is to be paid on each supply of services made for consideration by a taxable person. Nevertheless, their interpretation must be consistent with the objectives underlying the exemptions, and must comply with the requirements of the principle of fiscal neutrality inherent in the common system of VAT. Accordingly, the requirement of strict interpretation does not mean that those exemptions may be construed in such a way as to deprive them of their intended effects. (4)

19. Against that background, there are a number of reasons why I agree with the interpretation of Article 132(1)(d) of the VAT Directive suggested by the German and Hungarian Governments and the Commission.

20. At the outset, I observe that the VAT Directive defines neither ‘blood’ nor the other items listed in Article 132(1)(d) (‘human organs’ and ‘milk’). Nor has the Court, up to now, had the opportunity to provide guidance on those concepts. It is nevertheless clear that they must be given an autonomous and uniform interpretation specific to the EU rules on VAT. (5)

21. As regards the supply of products and services referred to in Article 132(1)(b) and (c) of the VAT Directive, the Court has stated that the objective of their exemptions is to reduce the cost of medical care and to make that care more accessible to individuals. (6) The ultimate aim of those exemptions is thus to avoid the products or services referred to in that provision becoming less accessible by reason of the increased costs that would result if their supply were subject to VAT. (7)

22. I believe that, to a certain extent, the same concern lies behind the exemptions laid down for the supply of the items listed in Article 132(1)(d) of the VAT Directive. The intention of the EU legislature was, therefore, to avoid an increase in the costs of certain health-related treatments that involve the supply of parts of, or products deriving from, the human body.

23. Seen in that light, ‘blood’ cannot but encompass its components, such as plasma.

24. It should not be overlooked, in this context, that — as pointed out by the German Government and the Commission — supplies of whole blood are, nowadays, a relatively rare occurrence. Even transactions effected for therapeutic purposes mostly involve the supply of blood components, such as plasma. The EU legislature which adopted the recast of the VAT Directive in 2006 could not have been unaware of that fact. The interpretation proposed by TMD, far from

being a narrow interpretation of the provision, would instead lead to a very significant reduction of the scope of application of the exemption provided for in respect of supplies of blood in Article 132(1)(d) of the VAT Directive. That interpretation would, consequently, largely frustrate the objective pursued by the legislature.

25. There are, moreover, other reasons why interpreting the term ‘blood’ as not encompassing its components would lead to consequences which are at odds with the objective pursued by the legislature. First, the costs of hospitals and establishments of a similar nature that use blood plasma for therapeutic purposes would obviously increase. Second, whereas the use of whole blood would be exempted, the use of one or more of its components would not. Accordingly, proportionally the cost of a supply of whole blood to a patient in need of a transfusion would be lower than the cost of a transfusion involving only plasma or only platelets. That cannot, to my mind, be the outcome sought by the legislature.

26. In addition, as the referring court notes, this interpretation is also borne out by the fact that, at its 99th meeting on 3 July 2013, the advisory committee on value added tax (the ‘VAT Committee’), agreed almost unanimously that the supply of ‘blood’ within the meaning of Article 132(1)(d) of the VAT Directive also encompasses, alongside the supply of whole blood, the supply of single blood components such as blood plasma or blood cells of human origin. While the guidelines issued by the VAT Committee are merely views of an advisory committee and not an official interpretation of EU law, and therefore are not binding, they nevertheless provide a useful aid to interpretation. (8)

27. That said, it is true — as the referring court also points out — that, apart from Directive 2009/132/EC, (9) other EU legal instruments also distinguish between ‘blood’ and ‘plasma’. Nevertheless, I do not see how that would affect the present analysis: different legal instruments may concern different matters and pursue different aims. (10) The same term, included in two or more legal instruments, may have different meanings. In any event, as the Commission rightly observes, even the legal instruments referred to by TMD in the present case do not subject whole blood and blood plasma to truly different legal regimes.

28. To begin with, Article 2(1) of Directive 2002/98/EC (11) refers to blood and blood components to make clear that the quality and safety standard provided in that directive apply with regard to both. Moreover, the distinction between human blood and blood plasma found in the combined nomenclature (12) serves only statistical purposes. In fact, all products listed in subheading 3002 (including both human blood and plasma) are exempt from customs duties. (13)

29. The fact that whole blood and blood plasma are now both exempt from customs duties lends further support to the view that both should also be exempt from VAT.

30. For those reasons, I propose that the Court answer the first question referred to the effect that, on a proper construction of Article 132(1)(d) of the VAT Directive, the term ‘blood’ encompasses blood plasma obtained from human blood.

B – *Question 2*

31. In the light of the proposed answer to the first question, it is also necessary to answer the second question referred. By its second question, the Hessisches Finanzgericht (Finance Court, Hesse) asks whether ‘blood’ also encompasses blood plasma that is not intended for therapeutic purposes, but exclusively for manufacturing medicinal products.

32. Again, TMD takes the view that the question should be answered in the negative, whereas the German and Hungarian Governments and the Commission are of the opinion that it should be

answered positively.

33. On this issue too, I agree with the interpretation of Article 132(1)(d) of the VAT Directive proposed by the latter.

34. I observe that, where Article 132(1) of the VAT Directive intends to restrict the exemptions provided therein to certain types of transactions — for example the supplies made by certain subjects (14) or entities, (15) to certain recipients, (16) for certain purposes, (17) or on certain conditions (18) — that is indicated expressly. Conversely, under point (d) of that provision, the transactions exempted are described in broad terms and are not subject to any specification or limitation. Article 132(1)(d) of the VAT Directive unequivocally states that, among the transactions to be exempted by the Member States are 'the supply of human organs, blood and milk'.

35. That seems to imply that the supply of blood (or its components) is to be exempted from VAT regardless of the final use of the blood or the purpose of the supply. Had the legislature intended otherwise, it presumably would have drafted a more explicit and elaborate provision, (19) as it did for all the other exemptions provided for in Article 132(1) of the VAT Directive.

36. TMD argues, however, that it can be inferred, by *a contrario* reasoning, from Articles 37 to 39 of Directive 2009/132 that a distinction should be made between therapeutic plasma and industrial plasma for the purposes of Article 132(1)(d) of the VAT Directive. According to Articles 37 to 39 of Directive 2009/132, importation of therapeutic substances of human origin (which include human blood and its derivatives) is to be exempted from VAT. In TMD's view, there would be no reason to expressly mention human blood and, especially, its derivatives if those products were already exempted under Article 132(1)(d) of the VAT Directive.

37. This argument fails to persuade me. First, it must be pointed out that Directive 2009/132 is a codification and recast of an earlier directive (Directive 83/181/EEC (20)) which had, in the meantime, been amended several times. (21) The express reference to blood and its derivatives can be explained by the fact that, when Directive 83/181 was adopted, blood and blood components were subject to different customs duties. This is no small detail: one of the key aims of Directive 83/181 then, and Directive 2009/132 now, is precisely to achieve the greatest possible degree of uniformity between the system for customs duties and that for VAT. It should be borne in mind, in this context, that Directive 2009/132 concerns exclusively exemptions on importation into the Union, whilst Article 132 of the VAT Directive is one of the general provisions on exemptions and is thus concerned with intra-Community transactions as well as with importation.

38. Second, Articles 37 to 39 of Directive 2009/132 cannot, in any event, have any bearing on the interpretation of Article 132 of the VAT Directive. Article 37(1) of Directive 2009/132 expressly states that it applies 'without prejudice to the exemption provided for in Article 143(a) of Directive 2006/112/EC'. The latter provision, in turn, states that Member States are to exempt transactions where 'the final importation of goods of which the supply by a taxable person would in all circumstances be exempt within their respective territory'. That obviously includes transactions, such as those involving the supply of blood, which are exempt under Article 132 of the VAT Directive. Therefore, and in very simple terms, Article 132(1)(d) of the VAT Directive cannot be interpreted in the light of Articles 37 to 39 of Directive 2009/132, let alone be regarded as being modified by those provisions. Because of the different scope and aims of the two legal instruments, it is not only possible but even logical that their provisions overlap to some extent.

39. TMD also argues that if Article 132(1)(d) of the VAT Directive were interpreted to encompass also the supply of blood plasma intended for manufacturing medicinal products, the final cost of those medicinal products would inevitably increase. This would run counter to the objective pursued by the provision in question to reduce costs in the health-care sector.

40. I must admit that this argument has some weight. It seems clear to me that, in certain cases, the exemption in question — as interpreted by the other parties that have submitted observations in the present proceedings — will have, *indirectly*, the effect of increasing the costs of the medicinal products manufactured on the basis of blood or its components. The reason is that an undertaking such as TMD cannot deduct the VAT paid on products or services purchased to run its business, from the VAT that, in its view, should be levied on the plasma it supplies to the pharmaceutical companies. Since its internal costs are higher because it is not possible to make deductions, that undertaking may need to sell plasma at higher prices, which might, in turn, affect the final price of the medicinal products manufactured from it. All things being equal, exempting plasma from VAT is likely to increase the price of those products.

41. However, it is unclear whether that increase in the price of the medicinal products of which blood plasma constitutes a component may be substantial. Indeed, that price will ultimately be influenced by a variety of factors, the price of the product's components being only one of those. The specific characteristics of the market, such as the presence (or absence) of competing products, the basic law of supply and demand and the possible constraints deriving from legislation on the pricing of medicinal products (that exists in many Member States) will also affect that price.

42. What appears crucial, in this context, is that all suppliers of blood plasma (and, in turn, all manufacturers of medicinal products which require blood plasma as a component) should be able to compete on an equal footing. That will clearly be the case, following delivery of judgment in these proceedings, since the interpretation that the Court gives, in this case, to the term 'blood' within the meaning of Article 132(1)(d) of the VAT Directive will be binding upon all Member States' tax authorities.

43. At any rate, as the German Government stressed, the fact that reducing the costs of certain products or services, by exempting their supply from VAT, may increase the operating costs of a taxable person appears inherent in the system of VAT conceived by the legislature. (22) It is inevitable that, for taxable persons, concluding transactions relating to VAT-exempt products or services may be less advantageous because of the manner in which the VAT system functions.

44. The legislature was thus aware of the particular situation of undertakings which need to conclude both taxable and non-taxable transactions and devised specific rules for that. In particular, Article 169 of the VAT Directive provides for the possibility, in certain cases, of deducting from the VAT which a taxable person is liable to pay the VAT levied on goods or services which are used for transactions which are exempt. However, the legislature chose to restrict the applicability of those rules to certain situations or transactions only.

45. Accordingly, the fact that the exempt transactions concluded by TMD do not give rise, under the VAT Directive, to a right to deduction, and that this situation might, in certain circumstances, lead to an increase in the cost of medical care, cannot lead to that provision being read in a way which seems at odds with its wording. An argument similar to that put forward in the present case by TMD has in fact already been rejected, precisely for the same reason, by the Court in the first *VDP Dental Laboratory* case. (23) After all, any lacuna in the system of exemptions relating to health-care products and services, is not for the Court but for the legislature to address. (24)

46. At this juncture, I would also call to mind that the Court has consistently held that, apart from minor provisions of goods which are strictly necessary at the time when the care is provided, the supply of drugs and other goods is physically and economically dissociable from the provision of the service and cannot therefore be exempted under Article 132(1) of the VAT Directive. (25)

47. That case-law implies that, although the overarching aim pursued by the legislature with some of the exemptions laid down in Article 132(1) of the VAT Directive was indeed to lower the cost of medical care, that lowering of costs did not concern medicinal products. In other words, considerations relating to the costs of medicinal products were not taken into account by the legislature when it adopted the provisions of Article 132(1) of the VAT Directive.

48. In this context, it may be worth pointing out that blood plasma is, clearly, not a medicinal product but, as explained, may be a component used in the production of medicinal products. Neither plasma destined for therapeutic purposes nor that intended for industrial use are mixed with any other substance, or processed in a way which alters their essential characteristics. The only process undertaken to obtain the product is that required to separate the different components of blood. The argument put forward by TMD seems to imply that any processing of the product before its supply would lead to a new or different product. That argument may, if pushed to its logical limits, lead to unreasonable results. For example, would the mere freezing of human milk for future infant feeding alter the tax treatment of that milk? Would the fact that an organ, after removal, may be infused with preservative solutions to allow storage and transport mean that the supply of that organ becomes subject to VAT?

49. It is significant that the same plasma can, in principle, be used both for therapeutic purposes and for the manufacturing of medicinal products. As TMD itself recognises, only the packaging, labelling and transport of plasma (and the controls carried out during process) may be different, depending on the intended use. Therefore, the plasma is, from the beginning until such time as it is employed by the different users, one and the same product.

50. Against that background, it seems to me that interpreting Article 132(1) of the VAT Directive as encompassing blood plasma regardless of its intended use is also more in line with the principle of fiscal neutrality, according to which economic operators carrying out the same transactions must not be treated differently in relation to the levying of VAT. (26)

51. In addition, as the referring court points out, since the product is essentially the same, it cannot be excluded — at least in theory — that plasma initially intended to be used for therapeutic purposes may subsequently be used for industrial purposes. If that is so, the German Government is quite right to argue that, were the tax authorities required to treat supplies of plasma differently according to their intended use (as declared by the relevant economic operators), the application of those rules would become uncertain and rather difficult to manage.

52. In the light of the above, the answer to the second question should, in my view, be that the term ‘blood’ in Article 132(1) of the VAT Directive also encompasses blood plasma that is intended

to be used for manufacturing medicinal products.

C – *Question 3*

53. In the light of the proposed answer to the second question, it is unnecessary to answer the third question referred.

IV – **Conclusion**

54. In conclusion, I propose that the Court answer the questions referred for a preliminary ruling by the Hessisches Finanzgericht (Finance Court, Hesse) as follows:

– the term ‘blood’ in Article 132(1)(d) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax encompasses the supply of blood plasma obtained from human blood;

– that term also encompasses blood plasma that is intended to be used for manufacturing medicinal products.

1 – Original language: English.

2 – Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ 2006 L 347 p. 1).

3 – Judgment of 26 February 2015 in *VDP Dental Laboratory and Others*, C?144/13, C?154/13 and C?160/13, EU:C:2015:116, paragraphs 43 and 44.

4 – See judgment of 12 March 2015 in *‘go fair’ Zeitarbeit*, C?594/13, EU:C:2015:164, paragraph 17 and the case-law cited.

5 – See, by analogy, judgment of 3 June 2010 in *De Fruytier*, C?237/09, EU:C:2010:316, paragraph 22.

6 – See judgment of 13 March 2014 in *Klinikum Dortmund*, C?366/12, EU:C:2014:143, paragraph 28.

7 – See, to that effect, judgment of 26 February 2015 in *VDP Dental Laboratory and Others*, C?144/13, C?154/13 and C?160/13, EU:C:2015:116, paragraph 46 and the case-law cited.

8 – See, Opinion of Advocate General Kokott in *RR Donnelley Global Turnkey Solutions Poland*, C?155/12, EU:C:2013:57, points 46 to 51.

9 – Council Directive of 19 October 2009 determining the scope of Article 143(b) and (c) of Directive 2006/112/EC as regards exemption from value added tax on the final importation of certain goods (OJ 2009 L 292, p. 5). On this directive, see *infra* points 36 to 38 of this Opinion.

10 – See, to that effect, by analogy, judgment of 17 January 2013 in *Commission* v *Spain*, C?360/11, EU:C:2013:17, paragraph 66.

11 – Directive of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30).

12 – 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 (OJ 1987 L 256, p. 1), as amended.

13 – Incidentally, this is another element which, to my mind, pleads in favour of treating human blood and blood plasma homogeneously also under the VAT Directive.

14 – Article 132(e), (f) and (j) of the VAT Directive.

15 – Article 132(a), (b), (g), (h), (i), (k), (l), (m), (n), (o), (p) and (q) of the VAT Directive.

16 – Article 132(f), (l), (m) and (p) of the VAT Directive.

17 – Article 132(f) and (k) of the VAT Directive.

18 – Article 132(f), (l) and (o) of the VAT Directive.

19 – See, by analogy, judgment of 28 November 2013 in *MDDP*, C?319/12, EU:C:2013:778, paragraph 29.

20 – Council Directive of 28 March 1983 determining the scope of Article 14(1)(d) of Directive 77/388/EEC as regards exemption from value added tax on the final importation of certain goods (OJ 1983 L 105, p. 38).

21 – See, in particular, recital 1 of Directive 2009/132.

22 – Cf. also the Opinion of Advocate General Kokott in *VDP Dental Laboratory*, C?401/05, EU:C:2006:537, point 96.

23 – Judgment of 14 December 2006 in *VDP Dental Laboratory*, C?401/05, EU:C:2006:792, paragraphs 34 to 36.

24 – See, to that effect, Opinion of Advocate General Sharpston in *Klinikum Dortmund*, C?366/12, EU:C:2013:618, point 57.

25 – See judgment of 13 March 2014 in *Klinikum Dortmund*, C?366/12, EU:C:2014:143, paragraph 33 and the case-law cited.

26 – See judgment of 17 December 2015 in *WebMindLicenses*, C?419/14, EU:C:2015:832, paragraph 41 and the case-law cited.