OPINION OF ADVOCATE GENERAL

Sharpston

delivered on 29 July 2010 (1)

Case C?156/09

Finanzamt Leverkusen

v

Verigen Transplantation Service International AG

(Reference for a preliminary ruling from the Bundesfinanzhof (Germany))

(VAT – Place of supply of services – Exemptions – Removal, multiplication and reimplantation of cartilage cells)

1. The main proceedings in this case concern the VAT treatment of a human tissue engineering technique in which cells are extracted from joint cartilage material taken from a patient, are multiplied in a laboratory and are prepared (with or without integration into a collagen membrane) for reimplantation into the patient's body.

2. The Bundesfinanzhof (Federal Finance Court), Germany, wishes to know whether the laboratory services constitute 'work on movable tangible property' for the purposes of European Union VAT legislation (if so, that would affect the place where they are deemed to be supplied when customer and supplier are in different Member States) or whether they are to be classified as 'the provision of medical care' (in which case they would be exempt from VAT).

Relevant Union VAT legislation

3. The main proceedings concern services provided in 2002, so that the relevant Union legislation is the Sixth Directive. (2)

4. Under Article 9(1) of that directive, the place where a service is supplied is deemed to be, essentially, the place of the supplier's business, fixed establishment, permanent address or usual residence. (3)

5. Article 9(2)(c) none the less specifies that the place of the supply of services relating to, inter alia, 'work on movable tangible property' is to be 'the place where those services are physically carried out'. (4)

6. However, Article 28b F of the directive provides:

'By way of derogation from Article 9(2)(c), the place of the supply of services involving valuations

or work on movable tangible property, provided to customers identified for value added tax purposes in a Member State other than the one where those services are physically carried out, shall be deemed to be in the territory of the Member State which issued the customer with the value added tax identification number under which the service was carried out for him.

This derogation shall not apply where the goods are not dispatched or transported out of the Member State where the services were physically carried out.' (5)

7. Article 13A(1) of the Sixth Directive lists exemptions from VAT 'for certain activities in the public interest'. It provides, in particular:

'Without prejudice to other Community provisions, Member States shall exempt the following under conditions which they shall lay down for the purpose of ensuring the correct and straightforward application of such exemptions and of preventing any possible evasion, avoidance or abuse:

…

(b) hospital and medical care and closely related activities undertaken by bodies governed by public law or, under social conditions comparable to 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;

…' (6)

Facts, procedure and questions referred

8. The Bundesfinanzhof explains that Verigen Transplantation Service International AG ('Verigen') is a biotechnology company established in Germany, operating in the field of tissue engineering. It researches, develops, produces and markets technologies to diagnose and treat human tissue diseases, in particular cartilage diseases. At issue are Verigen's transactions involving the multiplication of autologous chondrocytes (the patient's own joint cartilage cells) in cases where the customers to whom the service is supplied (doctors or clinics) are resident in other Member States and Verigen has stated their VAT identification number in its invoices.

9. The doctor or clinic sends Verigen biopsy cartilage material taken from the patient. Verigen treats the tissue to make it possible to remove the chondrocytes. After preparation in their own blood serum in an incubator they are multiplied through growth, normally within three to four weeks. The resulting cells may, or may not, be introduced into a collagen membrane to produce a 'cartilage plaster'. In either event, they are sent to the patient's doctor or clinic to be reimplanted.

10. Verigen treated those services as not liable to VAT when provided to customers in other Member States. The tax authority however considered them to be taxable and assessed tax for the year in issue.

11. In the ensuing proceedings, Verigen argued that the multiplication of cartilage cells did not constitute the provision of medical care. Rather, it involved 'routine laboratory services' carried out by biotechnical or medical-technical assistants. The necessary quality controls were carried out by a pharmacist and an external chemist.

12. The Finanzgericht (Finance Court) upheld Verigen's challenge at first instance. It ruled that the cell multiplication was a service which had to be regarded as 'work on movable tangible

property'. On separation from the body, organs taken for transplantation also constituted movable property. Whether the separated body part was subsequently used for transplantation in the same patient or a different one could have no bearing on whether or not it was subsumed under the term 'movable tangible property'. Verigen's invoices showed that customers resident in other Member States used the VAT identification numbers issued to them in their home States. The transactions were therefore not taxable in Germany.

13. In its appeal on a point of law, the tax authority contends that the cells do not become movable property as a result of their short-term separation from the body, and the cell multiplications do not constitute 'work'. Nor is there any 'use' of the VAT identification number issued in the other Member State – that would have required an express agreement prior to the supply of the service.

14. The referring court considers that the delivery of the multiplied cartilage cells to the patient's doctor or clinic is not a supply of goods but that the cell multiplication is a service, since Verigen cannot dispose freely of the cartilage material as owner but is required to return the cells following multiplication. Cell multiplication is not taxable in Germany when that service is supplied in another Member State. That is the case however only if, on a proper construction, Article 28b F of the Sixth Directive covers Verigen's service. If that is not the correct interpretation of Article 28b F, the transaction must be taxable in Germany unless it can be regarded as constituting the provision of medical care within the meaning of Article 13A(1)(c).

15. The Bundesfinanzhof therefore seeks a ruling on the following questions:

'1. Is the first paragraph of Article 28b F of [the Sixth Directive] to be interpreted as meaning that:

(a) cartilage material … which is taken from a human being and entrusted to an undertaking for the purpose of cell multiplication and subsequent return as an implant for the patient concerned constitutes "movable tangible property" for the purposes of this provision,

(b) the removal of joint cartilage cells from the cartilage material and the subsequent cell multiplication constitute "work" on movable tangible property for the purposes of this provision,

(c) the service has been supplied to a customer "identified for valued added tax purposes" simply if the value added tax identification number is stated in the invoice of the supplier of the service, without any express written agreement as to its use having been made?

2. If any of the above questions is answered in the negative:

Is Article 13A(1)(c) of [the Sixth Directive] to be interpreted as meaning that the removal of the joint cartilage cells from the cartilage material taken from a human being and the subsequent cell multiplication constitute the "provision of medical care" where the cells obtained from the cell multiplication are reimplanted in the donor?'

16. Written observations have been submitted by the German and Spanish Governments, and by the Commission. No hearing was requested and none was held. It was decided by the Court that the present Opinion would be deferred to take account of the judgments in *CopyGene* (7) and *Future Health Technologies*, (8) which concern matters related to the second question. Those judgments were delivered on 10 June 2010.

Assessment

17. Although the referring court poses its second question only in the event of a negative

answer to the first, the order of the questions could readily be reversed. If, as the Commission suggests, the service in issue does in fact constitute the provision of medical care within the meaning of Article 13A(1)(c) of the Sixth Directive, the transactions will be exempt regardless of where they are (deemed to be) carried out. I shall therefore address the second question first.

The second question

18. The case-law on the notion of medical care or the provision of medical care has most recently been set out in *CopyGene* and *Future Health Technologies*, (9) and may be summarised as follows.

19. The exemptions in Article 13 of the Sixth Directive are independent concepts of European Union law whose purpose is to avoid divergences in the application of the VAT system as between Member States. They are not aimed at exempting every activity performed in the public interest, but only those listed and described in detail. The terms used are to be interpreted strictly, as exceptions to the general principle that VAT is to be levied on all goods and services supplied for consideration by a taxable person. Nevertheless, their interpretation must be consistent with the objectives pursued by the exemptions and must comply with the principle of fiscal neutrality inherent in the VAT system. Thus, the requirement of strict interpretation must not lead to depriving the exemptions of their intended effect.

20. As regards medical services, Article 13A(1)(b) covers all services supplied in a hospital environment while Article 13A(1)(c) covers medical services provided outside such a framework – at the address of the person providing the care, at the patient's home or in any other place. Article 13A(1)(b) and (c), which have separate fields of application, are thus intended to regulate all exemptions of medical services in the strict sense.

21. Consequently, the concept of 'medical care' in Article 13A(1)(b) and that of 'the provision of medical care' in Article 13A(1)(c) are both intended to cover services which have as their purpose the diagnosis, treatment and, in so far as possible, cure of diseases or health disorders. Whilst both services must have a therapeutic aim, it does not necessarily follow that the therapeutic purpose must be confined within a particularly narrow compass. Both exemptions have, moreover, the objective of reducing the cost of health care.

22. In the present case, both the Commission and the German Government consider that the service in issue pursues a therapeutic aim. The Spanish Government disagrees, on the very brief ground that it involves only routine laboratory processes in the field of tissue engineering. I agree with the Commission and the German Government.

23. It is not contested, and cannot be doubted, that the process described – removal, multiplication and reimplantation of autologous chondrocytes – has, overall, a therapeutic purpose. The specific services provided by Verigen form, admittedly, only part of that overall process. However, they are an essential, inherent and inseparable part of the process, none of the stages of which can usefully be performed in isolation from the others.

24. The services in issue are therefore of a kind covered by the concept of ‘provision of medical care’ in Article 13A(1)(c) of the Sixth Directive. Nor is there any reason to exclude them from exemption on the ground that they are carried out by laboratory staff who are not qualified medical practitioners. As the Commission notes, it is not necessary for every aspect of therapeutic care to be provided by medical staff. (10) It has, indeed, specifically been held that medical tests prescribed by general practitioners and carried out by an outside private laboratory may fall within the concept of medical care or the provision of medical care, even though they may precede any ascertained need for specific treatment. (11)

25. Furthermore, as the German Government points out, it is not necessary to make classification as medical care or the provision of medical care dependent (as the wording of the national court’s question might suggest) on reimplantation of the multiplied cells into the patient from whom they were originally removed. Blood transfusions and organ transplants, from the body of one person to another, clearly constitute medical care or the provision of medical care. (12)

26. However, the German Government also suggests – though without proposing any firm conclusion – that to classify the services in issue as the provision of medical care might run counter to the principle of fiscal neutrality (in the sense of avoiding distortions of competition (13)) in that the ‘cartilage plaster’ produced is functionally comparable to a pharmaceutical product, which would not be exempt from VAT, but could only be subject to a reduced rate. (14)

27. I am not convinced.

28. Classification of a service as medical care or the provision of medical care cannot depend on whether a pharmaceutical alternative is available. Some kinds of such care already have pharmaceutical alternatives while others do not but are likely to do so in the future, so that the two categories are in constant evolution. Indeed, many types of goods and services may be substitutable for others, in different VAT categories, in certain circumstances. However (without prejudice to each Member State’s right, within the scope of the discretion allowed to it by the Sixth Directive, to subject certain exemptions to conditions designed to avoid distortion of competition – of which there is no suggestion in the present case), whether a service constitutes medical care or the provision of medical care can depend only on its own nature and not on the nature of alternatives.

29. I would point out, moreover, that it is far from obvious whether an exempt service (which bears no output VAT but on the cost components of which no input tax can be deducted) is likely to be at a competitive advantage or disadvantage in comparison with a product bearing output VAT at a reduced rate, with the right to deduct input tax.

30. I therefore consider that services of the kind described fall within the concept of medical care or the provision of medical care in Article 13A(1) of the Sixth Directive, and are thus to be exempted from VAT in accordance with subparagraph (b) or (c) thereof, as the case may be. It is unnecessary to establish the place of supply of such services, since they fall within the exemption wherever they are supplied.

The first question

31. In view of the answer which I propose to the national court’s second question, there is no need to answer its first question. None the less, I shall offer the following brief comments in case the Court should decide to answer the question.

32. The first part of the question is whether the biopsy cartilage material in question constitutes

‘movable tangible property’ for the purposes of Article 28b F of the Sixth Directive. All those submitting observations consider that it does, and I agree.

33. The cartilage cells are undeniably both movable (as the German Government notes, the issue arises only because they are sent from one Member State to another) and tangible. And, whilst human cells may not form the most typical kind of ‘property’ or ‘goods’, (15) it is none the less clear that they are easily capable of falling within that category. (16)

34. The second part of the question is whether the procedures carried out by Verigen constitute ‘work’ on those cells for the purposes of the same provision. Again, those submitting observations consider that they do and, again (if the second question were to be answered in the negative), I agree.

35. In *Linthorst, Pouwels and Scheren*, (17) the Court noted that the phrase ‘work on movable tangible property’ calls to mind, in common parlance, purely physical action which is, by nature, in principle neither scientific nor intellectual, and does not include the principal duties of a veterinary surgeon, basically consisting in the treatment of animals in accordance with scientific rules – which, even if it may necessitate physical action on the animal, is not sufficient for it to be described as work.

36. It will be for the national court to determine whether the procedures carried out by Verigen are ‘scientific’ or ‘intellectual’ in that sense. It seems to me that the dividing line which the Court was endeavouring to draw there lies between merely routine application of accepted scientific knowledge or skills and the involvement of innovation, based on such knowledge or skills, in, for example, interpreting data or adapting procedures. The order for reference suggests that the services in issue fall within the former category.

37. The third part of the question is, essentially, whether the phrase ‘customers identified for value added tax purposes’ in Article 28b F of the Sixth Directive concerns all those whose VAT identification number is stated in the invoice or only those who have agreed in writing to the use of that number in the invoice. Here, the German Government and the Commission (the Spanish Government has not voiced an opinion) differ.

38. The German Government submits, essentially, that the reference to the VAT identification number ‘under which’ the service was carried out for the customer requires a tacit or express bilateral agreement that taxation should be subjected to the arrangement set out in Article 28b F. That, it says, would provide legal certainty, by contrast with a situation in which the supplier unilaterally indicates (or not) the customer’s VAT identification number, leaving the customer in doubt, until the invoice is issued, as to who will be liable for the tax.

39. The Commission points out that the system set up by Article 28b F exempts the supply from VAT in the Member State in which it is provided while making the customer liable for (deductible) input tax in his or her own State – a simplification of the procedure which would otherwise have prevailed under the Eighth Directive. (18) It should apply whenever the customer informs the supplier (for example, in the document placing the order) that he has a VAT identification number in his own Member State. No other conditions are required. If application of the system were made dependent on agreement between the parties, the place of supply would no longer be uniform, as intended by Directive 95/7. (19)

40. I would endorse the Commission’s submissions in that regard.

Conclusion

41. In the light of the above considerations, I am of the opinion that the Court should give the following reply to the Bundesfinanzhof:

On a proper construction of Article 13A(1)(c) of Sixth Council Directive 77/388/EEC, of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes – Common system of value added tax: uniform basis of assessment, the removal of joint cartilage cells from biopsy cartilage material taken from a human being and their subsequent multiplication, with a view to reimplantation for therapeutic purposes, constitute the 'provision of medical care', regardless of whether the cells obtained from the cell multiplication are intended for reimplantation in the donor or in another person.

1 – Original language: English.

2 – Sixth Council Directive 77/388/EEC of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes – Common system of value added tax: uniform basis of assessment (OJ 1977 L 145, p. 1), replaced, with effect from 1 January 2007, by Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax (OJ 2006 L 347, p. 1), which presents the same provisions in a recast structure and wording.

3 – See Article 45 of Directive 2006/112.

4 – See Article 52(c) of Directive 2006/112.

5 – See Article 55 of Directive 2006/112. Article 28b F was introduced by Council Directive 95/7/EC of 10 April 1995 amending Directive 77/388/EEC and introducing new simplification measures with regard to value added tax – scope of certain exemptions and practical arrangements for implementing them (OJ 1995 L 102, p. 18), recital 10 in the preamble to which specifies that the aim was to facilitate intra-Community trade in the field of work on movable tangible property.

6 – See Articles 131 and 132(1)(b) and (c) of Directive 2006/112.

7 – Case C?262/08 [2010] ECR I?0000.

8 – Case C?86/09 [2010] ECR I?0000.

9 – Cited above in footnotes 7 and 8, respectively. See in particular paragraphs 24 to 30 of *CopyGene* and paragraphs 28 to 30, 36, 37 and 40 of *Future Health Technologies*, together with the case-law cited there. See also my Opinion in *CopyGene*, point 30 et seq.

10 – See Case C?141/00 *Kügler* [2002] ECR I?6833, in particular paragraph 41.

11 – See Case C?106/05 *L.u.P.* [2006] ECR I?5123, in particular paragraph 39.

12 – See, by analogy, *CopyGene*, paragraph 51 of the judgment and point 46 et seq. of my Opinion.

13 – It may be noted that (although not strictly relevant to the present analysis) Article 13A(2)(a) of the Sixth Directive allows Member States to make the granting to bodies not governed by public law of each exemption provided for in, inter alia, Article 13A(1)(b) subject to certain conditions, in particular (fourth indent) that exemption must not be likely to create distortions of competition such as to place at a disadvantage commercial enterprises liable to VAT.

14 – Article 12(3)(a), third indent, of the Sixth Directive, in conjunction with point 3 of Annex H thereto (Article 98(1) and (2) of Directive 2006/112 and point 3 of Annex III thereto).

15 – The terms ‘goods’ and ‘property’ are used in different provisions of the English language version of the Sixth Directive, seemingly interchangeably, where other language versions use a single term.

16 – A macabre, tragic and controversial example is the case of HeLa cells, originally taken from the body of a woman who died in the United States in 1951, since multiplied in an ‘immortal cell line’ totalling several times her live body weight and used for medical research throughout the world (see Rebecca Skloot, *The Immortal Life of Henrietta Lacks*, Crown, New York, 2010).

17 – Case C?167/95 [1997] ECR I?1195, paragraph 15 et seq.

18 – Eighth Council Directive 79/1072/EEC of 6 December 1979 on the harmonisation of the laws of the Member States relating to turnover taxes – Arrangements for the refund of value added tax to taxable persons not established in the territory of the country (OJ 1979 L 331, p. 11).

19 – See footnote 5 above.