JUDGMENT OF THE COURT (Third Chamber)

10 June 2010 *

In Case C-262/08,

REFERENCE for a preliminary ruling under Article 234 EC from the Østre Landsret (Denmark), made by decision of 13 June 2008, received at the Court on 19 June 2008, in the proceedings

CopyGene A/S

v

Skatteministeriet,

* Language of the case: Danish.

THE COURT (Third Chamber),

composed of J.N. Cunha Rodrigues, President of the Second Chamber, acting for the President of the Third Chamber, P. Lindh, A. Rosas, A. Ó Caoimh (Rapporteur) and A. Arabadjiev, Judges,

Advocate General: E. Sharpston,
Registrar: R. Şereş, Administrator,

having regard to the written procedure and further to the hearing on 14 May 2009,

after considering the observations submitted on behalf of:

— CopyGene A/S, by A. Hedetoft and M. Andersen, advokater,

— the Danish Government, by B. Weis Fogh, acting as Agent, and D. Auken, advokat,

— the Greek Government, by K. Georgiadis, I. Bakopoulos, G. Kanellopoulos and I. Pouli, acting as Agents,

— the Commission of the European Communities, by H. Støvlbæk and D. Triantafyllou, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 10 September 2009,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 13A(1)(b) 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 (OJ 1977 L 145, p. 1; 'the Sixth Directive').

2 The reference was made in the course of proceedings between CopyGene A/S ('CopyGene') and the Skatteministeriet (Ministry of Taxation) concerning the refusal of the Danish tax authorities to exempt from value added tax ('VAT') services offered by CopyGene consisting in the collection, transportation, analysis and storage of blood from the umbilical cord ('cord blood') for the purpose of using stem cells from that blood for possible future medical treatment, either 'autologous' or, as the case may be, 'allogeneic'.

Legal context

European Union law

The Sixth Directive

3 Article 2(1) of the Sixth Directive makes 'the supply of goods or services effected for consideration within the territory of the country by a taxable person acting as such' subject to VAT.

4 Article 13A(1)(b) and (c) of the Sixth Directive provide:

'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;

…'

5 Article 13A(2)(a) of the Sixth Directive provides that Member States may make the granting to bodies other than those governed by public law of the exemption provided for in paragraph (1)(b) of that article subject, in each individual case, to one or more of the conditions it lays down.

6 Article 13A(2)(b) provides:

'The supply of services or goods shall not be granted exemption as provided for in (1)(b), (g), (h), (i), (l), (m) and (n) above if:

— it is not essential to the transactions exempted,

— its basic purpose is to obtain additional income for the organisation by carrying out transactions which are in direct competition with those of commercial enterprises liable for value added tax.'

Directive 2004/23/EC

7 In the words of Article 1 of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ 2004 L 102, p. 48), that directive 'lays down standards of quality and safety for human tissues and cells intended for human applications ...'.

8 Recital 1 in the preamble to that directive states that the transplantation of human tissues and cells 'is a strongly expanding field of medicine offering great opportunities for the treatment of as yet incurable diseases'. Recital 7 in the preamble states that the directive should apply to umbilical cord stem cells.

9 Article 3(p) and (q) of the directive define allogeneic use as cells or tissues removed from one person being applied to another, and autologous use as cells or tissues being removed from and applied in the same person.

10 Under Article 6(1) of Directive 2004/23, Member States are to ensure that all tissue establishments where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

National legislation

11 It is common ground in the main proceedings that Paragraph 13(1)(1) of the Law on VAT (momsloven) must be interpreted in accordance with Article 13A(1)(b) of the Sixth Directive.

12 Directive 2004/23 was transposed into Danish law by the Law on the requirement for quality and safety in handling human tissues and cells (vævsloven).

13 The activities of stem cell banks are regulated in Denmark by, in particular, the Law on the marketing of health services (lov om markedsføring af sundhedsydelser), the Law on the protection of personal data (persondataloven) and the Law on patients' rights (lov om patienters retsstilling). It is apparent from the Court file that the last-mentioned law has been supplemented by several administrative guidelines, including Guidelines No 83 of 22 September 1998 on biobanks in the health sector: patients' rights and official requirements (vejledning nr. 83 of 22 September 1998 om biobanker inden for sundhedsområdet: Patientrettigheder og mydighedskrav).

The main proceedings and the questions referred for a preliminary ruling

14 The Østre Landsret (Eastern Regional Court) explains that stem cells are immature cells capable of reproducing themselves and of renewing other specialised cells in the body. They can be extracted from embryos, cord blood, bone marrow or peripheral blood, and are used to treat diseases in which special cells are absent or have been destroyed. That court states that stem cells from cord blood ('cord stem cells') have been used since 1988.

15 In the long term, according to the referring court, it should be possible to use stem cells in treatments for diabetes, rheumatism, cancer, Parkinson's and Alzheimer's diseases and cystic fibrosis. It adds that research is being carried out worldwide into further development of their possible therapeutic uses. However, the decision for reference states that not all kinds of stem cell can be used to treat all types of disease. In some cases, cord stem cells are preferable.

16 CopyGene is described in the decision for reference as being 'Scandinavia's largest privately owned biobank'. It offers to prospective parents the collection, transportation, analysis and storage of cord blood of newborn children with a view to using the cord stem cells contained in it to treat the child in the event of serious disease. Those services are not covered or reimbursed by the Danish public health insurance scheme.

17 First, the future parents sign a contract with CopyGene for the blood to be collected, transported and analysed. The blood is drawn off immediately after birth by authorised medical personnel who are also contractually bound to CopyGene. It is next transported to CopyGene's laboratory and then analysed to establish whether there

are sufficient live stem cells to justify their storage. If there are, the parents can conclude a further renewable contract with CopyGene for the cryopreservation (freezing) and storage of the cells.

18 The stem cells in question can be used only for hospital care. The blood is the property of the child, represented by its mother. CopyGene does not own the stem cells and has no right to use them for research, transplantation or other purposes.

19 In accordance with the Law on the requirement for quality and safety in handling human tissues and cells, CopyGene is authorised to handle cord stem cells for 'autologous' use. Following the purchase of another Danish biobank, which is authorised to handle stem cells for both autologous and allogeneic use, CopyGene entered into negotiations with the Danish authorities about unifying the systems of the two stem cell banks so that all the stem cell samples, both previously frozen and new, would undergo the same process of analysis and could be used both autologously and allogeneicly. CopyGene stated in its written observations that it expected to obtain an authorisation to do so in the course of 2009.

20 By decision of 1 July 2004, the Told- og Skattestyrelsen (Customs and Tax Directorate) rejected an application for exemption from VAT for the services at issue in the main proceedings. CopyGene's complaint against that decision was dismissed on 21 October 2005 by the Landsskatteretten (National Tax Tribunal).

21 CopyGene appealed to the referring court against the refusal to grant the exemption applied for, arguing that its supplies of services should be regarded as being 'closely related' to hospital and medical care and, consequently, should be exempted from VAT under Article 13A(1)(b) of the Sixth Directive.

22 In those circumstances, the Østre Landsret decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is the term activity "closely related" to hospital care in Article 13A(1)(b) of the Sixth Directive to be interpreted as implying a temporal requirement so that the hospital care to which the service is closely related must exist or be specifically performed, commenced or envisaged, or is it sufficient that the service will potentially be closely related to possible, but as yet non-existent or undetermined future hospital care, so that the services supplied by a stem cell bank, consisting in the collection, transportation, analysis and storage of umbilical cord blood from newborns for autologous use, are covered by it?

In that connection, is it relevant that the services described cannot be performed at a later time than the time of delivery?

(2) Is Article 13A(1)(b) of the Sixth Directive to be interpreted as covering general preventive services where the services are supplied before the hospital or medical care takes place and before the hospital or medical care is required in both temporal and health terms?

(3) Is the term "other duly recognised establishments of a similar nature" in Article 13A(1)(b) of the Sixth Directive to be interpreted as covering private stem cell banks where the services – which are performed and supplied by professional health personnel in the form of nurses, midwives and bioanalysts – consist in the collection, transportation, analysis and storage of umbilical cord blood from newborns with a view to autologous use in connection with possible future hospital care where the stem cell banks concerned do not receive support from the public heath insurance scheme and where the expenditure on the services provided by these stem cell banks is not covered by the public health insurance scheme?

In that connection, is it relevant whether or not a private stem cell bank has obtained authorisation from a Member State's competent health authorities to handle tissue and cells – in the form of processing, preserving and storing stem cells from umbilical cord blood for autologous use – pursuant to national legislation which implements Directive 2004/23 …?

(4) Is the answer to Questions 1 to 3 affected by whether the above services are supplied with a view to possible allogeneic use and provided by a private stem cell bank which has obtained authorisation from a Member State's competent health authorities to handle tissue and cells – in the form of processing, preserving and storing stem cells from umbilical cord blood for autologous use – pursuant to national legislation which implements Directive 2004/23 …?'

The questions referred

Preliminary observations

23 Under the Sixth Directive, the scope of VAT is very wide in that Article 2 thereof, which concerns taxable transactions, refers not only to imports of goods but also to the supply of goods or services effected for consideration within the territory of the country by a taxable person acting as such (see, in particular, Case C-255/02 *Halifax and Others* [2006] ECR I-1609, paragraph 49; Case C-401/05 *VDP Dental Laboratory* [2006] ECR I-12121, paragraph 22; and Case C-88/09 *Graphic Procédé* [2010] ECR I-1049, paragraph 15). Article 13 of the Sixth Directive nevertheless exempts certain activities from VAT.

24 It is settled case-law that the exemptions referred to in Article 13 of the Sixth Directive constitute independent concepts of European Union law whose purpose is to avoid divergences in the application of the VAT system as between one Member State and another (see, in particular, Case C-349/96 *CPP* [1999] ECR I-973, paragraph 15, and Case C-473/08 *Eulitz* [2010] ECR I-907, paragraph 25).

25 The Court has also consistently held that the exemptions in Article 13A of the Sixth Directive are not aimed at exempting from VAT every activity performed in the public interest, but only those which are listed and described in great detail in it (see, in particular, Case 107/84 *Commission* v *Germany* [1985] ECR 2655, paragraph 17; Case C-307/01 *D'Ambrumenil and Dispute Resolution Services* [2003] ECR I-13989, paragraph 54; and *Eulitz*, paragraph 26, and the case-law cited).

26 The terms used to specify the exemptions in Article 13 of the Sixth Directive are to be interpreted strictly, since they constitute exceptions to the general principle that VAT is to be levied on all goods and services supplied for consideration by a taxable person. Nevertheless, the interpretation of those terms must be consistent with the objectives pursued by those exemptions and comply with the requirements of the principle of fiscal neutrality inherent in the common system of VAT. Thus, the requirement of strict interpretation does not mean that the terms used to specify the exemptions referred to in Article 13 should be construed in such a way as to deprive the exemptions of their intended effect (see, in particular, Case C-445/05 *Haderer* [2007] ECR I-4841, paragraph 18, and the case-law cited, and *Eulitz*, paragraph 27, and the case-law cited).

27 As regards medical services, it is clear from the case-law that Article 13A(1)(b) of the Sixth Directive covers all services supplied in a hospital environment while Article 13A(1)(c) thereof covers medical services provided outside such a framework, both at the private address of the person providing the care and at the patient's home or at any other place (see, to that effect, Case C-141/00 *Kügler* [2002] ECR I-6833, paragraph 36). It follows that Article 13A(1)(b) and (c) of the Sixth Directive, which have separate fields of application, are intended to regulate all exemptions of medical services in the strict sense (see *Kügler*, paragraph 36, and Case C-106/05 *L.u.P.* [2006] ECR I-5123, paragraph 26).

28 It follows, as the Court has previously ruled, that the concept of 'medical care' in Article 13A(1)(b) of the Sixth Directive 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 (see Case C-45/01 *Dornier* [2003] ECR I-12911, paragraph 48, and the case-law cited, and *L.u.P.*, paragraph 27).

29 Whilst 'medical care' and 'the provision of medical care' must have a therapeutic aim, it does not necessarily follow that the therapeutic purpose of a service must be confined within a particularly narrow compass (see Case C-76/99 *Commission* v *France* [2001] ECR I-249, paragraph 23, and Case C-212/01 *Unterpertinger* [2003] ECR I-13859, paragraph 40).

30 Thus the Court has already ruled that medical services effected for prophylactic purposes may benefit from exemption under Article 13A(1)(b) or (c) of the Sixth Directive. Even in cases where the persons who are the subject of examinations or other medical intervention of a prophylactic nature are not suffering from any disease or health disorder, the inclusion of those services within the meaning of 'medical care' and 'the provision of medical care' is consistent with the objective of reducing the cost of healthcare, which is common to both the exemption under Article 13A(1)(b) of the Sixth Directive and that under (c) of that paragraph (see, to that effect, *L.u.P.*, paragraph 29, and the case-law cited). Accordingly, medical services supplied for the purpose of protecting, including maintaining or restoring, human health may benefit from the exemption under Article 13A(1)(b) and (c) of that directive (see, to that effect, *Unterpertinger*, paragraphs 40 and 41, and *D'Ambrumenil and Dispute Resolution Services*, paragraphs 58 and 59).

31 It is in the light in particular of those considerations that the questions referred must be answered.

The first and second questions, read in conjunction with the fourth question

32 By its first two questions, read in conjunction with the fourth question, the referring court seeks, in essence, to determine whether the collection, transportation, analysis and storage of cord blood with a view to the possible use of the stem cells in it for the purposes of future autologous medical treatment can be covered by the exemption from VAT under Article 13A(1)(b) of the Sixth Directive, as an activity 'closely related' to 'hospital and medical care' within the meaning of that provision.

33 In that context, by its first question, the referring court is asking, in essence, whether the concept of activities 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive is to be interpreted as meaning that it can cover activities such as those at issue in the main proceedings, even though the possible hospital care in question has not necessarily been performed, commenced or yet envisaged. The second question seeks more particularly to ascertain, in essence, whether Article 13A(1)(b) of the Sixth Directive encompasses, as preventive services, activities such as those at issue in the main proceedings. The fourth question concerns also, particularly, the point whether the possibility of a taxable person such as CopyGene being authorised to supply services with a view to both autologous and allogeneic uses has any bearing on the reply to be given to those first two questions.

34 As regards, first of all, the point, raised by the second question, whether Article 13A(1)(b) of the Sixth Directive encompasses, as preventive services, activities such as those at issue in the main proceedings, it is already clear from paragraph 30 of the present judgment that preventive medical services can come within the meaning of 'medical care' for the purposes of that provision.

35 However, in the present case, neither the referring court nor any of the parties which have submitted observations to the Court has suggested that the activities at issue in the main proceedings come themselves within the meaning of 'medical care' in Article 13A(1)(b) of the Sixth Directive.

36 In any event, while the detection of illness may admittedly be one of the possible purposes for collecting cord stem cells, it appears, from the file before the Court, that the services provided by CopyGene seek only to ensure that a particular resource will be available for medical treatment in the uncertain event that it becomes necessary, but they do not constitute, as such, activities seeking to avert, avoid or prevent disease, injury or health problems, or to detect latent or incipient conditions. Were that the case, which it is, where necessary, for the referring court to determine, activities such as those at issue in the main proceedings could not be regarded as being, by themselves, preventive.

37 On the other hand, if the referring court concluded that the analysis of cord blood actually has a medical diagnostic purpose and does not merely form part of the tests to determine whether the stem cells are viable, the conclusion would follow that there was a supply of diagnostic care within the exemption laid down in Article 13A(1)(b) of the Sixth Directive, subject to compliance with the other requirements laid down by that provision and by that directive.

38 As regards, next, the concept of activities 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive, it is apparent from the very terms of that provision that it does not envisage services which are unrelated to hospital care for the patients receiving those services or to any medical care which they might receive (see *Dornier*, paragraph 33, and Joined Cases C-394/04 and C-395/04 *Ygeia* [2005] ECR I-10373, paragraph 17).

39 Accordingly, the Court ruled that services fall within the concept of 'activities closely related' to hospital or medical care appearing in Article 13A(1)(b) of the Sixth Directive only when they are actually supplied as a service ancillary to the hospital or medical care received by the patients in question and constituting the principal service (see *Ygeia*, paragraph 18).

40 In that regard, it follows from the case-law that a service may be regarded as ancillary to a principal service if it does not constitute an end in itself, but a means of better enjoying the supplier's principal service (see *Commission* v *France*, paragraph 27; *Dornier*, paragraph 34; *Ygeia*, paragraph 19; and Case C-434/05 *Horizon College* [2007] ECR I-4793, paragraph 29, and the case-law cited). As regards medical services, the Court has stated that, taking account of the objective pursued by the exemption provided for in Article 13A(1)(b) of the Sixth Directive, only the supply of services which are logically part of the provision of hospital and medical-care services, and which constitute an indispensable stage in the process of the supply of those services to achieve their therapeutic objectives, is capable of amounting to 'closely related activities' within the meaning of that provision (see, to that effect, *Ygeia*, paragraph 25).

41 In this case, it appears from the Court file that, by reason of among other things the relevant Danish legislation and the contract between CopyGene and the client parents, the cord stem cells concerned by the activities at issue in the main proceedings can be used only for medical treatment, namely transplants, to the exclusion of all other purposes, for example that of research.

42 It is apparent from the file before the Court that such treatment involves the carrying-out of complex medical interventions which are usually, if not always, performed in a hospital environment. Since such treatment is intended to treat and, in so far as possible, to cure diseases or health disorders, it comes within, as follows from paragraph 28 of the present judgment, the concept of 'medical care' in Article 13A(1)(b) of the Sixth Directive.

43 The Danish and Greek Governments as well as the Commission of the European Communities argue however, in essence, that the activities at issue in the main proceedings present, in the current state of scientific knowledge, so distant and hypothetical a link with the possible future hospital care of the persons concerned that there can be no question of their being activities closely related to hospital and medical care within the meaning of Article 13A(1)(b) of the Sixth Directive.

44 In that regard, as is clear from paragraph 24 of the present judgment, the exemptions referred to in Article 13 of the Sixth Directive constitute independent concepts of European Union law. Therefore, it is not appropriate in this case to base the interpretation of Article 13A(1)(b) of that directive principally on the 'current' state of scientific knowledge, all the more so as it is clear from the contents of the file before the Court that, in the field subject to this reference for a preliminary ruling, the state of scientific knowledge is constantly developing. It is very difficult for courts to evaluate that state with confidence in a field such as that at issue in the main proceedings.

45 Further, the exemption provided for in Article 13A(1)(b) of the Sixth Directive does not impose what the referring court describes, in its first question, as a 'temporal requirement'. Neither the purpose of that exemption nor the general scheme of the Sixth Directive requires that provision to be interpreted as if there were such a requirement. Thus, the possibility put forward in that question that there could be a long period of time between the collection of the cord stem cells concerned and their possible future use for the purposes of hospital or medical care does not, as such, preclude activities such as those at issue in the main proceedings from coming within that exemption, all the more so since, as the referring court points out in the second

part of the first question, it is impossible to collect blood containing cord stem cells otherwise than at birth.

46 However, it does not follow that the activities at issue in the main proceedings could be regarded as being services which are 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive.

47 In that regard, it is established that, whatever the precise figures derived from the current state of scientific knowledge may be, in the case of the majority of the recipients of the activities at issue in the main proceedings, there is not and probably never will be a principal service coming within the concept of 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive. Thus, the first question is based on the premiss that, when services such as those at issue in the main proceedings are supplied, there is usually no hospital or medical care which has been performed, commenced, necessitated or determined, or even envisaged in its major aspects.

48 Indeed, it is only in the double eventuality that, first, the state of medical science enables or requires use of cord stem cells for the treatment or prevention of a given illness and, second, that illness presents or is likely to present in a specific case that a sufficiently close link would exist between, on the one hand, the hospital and medical care which would constitute the principal service and, on the other, the activities at issue in the main proceedings.

49 In those circumstances, even accepting that the activities at issue in the main proceedings could have no purpose other than that of using the cord stem cells thus preserved in connection with medical care provided in a hospital environment and could not be diverted to other uses, those activities cannot be regarded as actually being supplied as services ancillary to the hospital or medical care received by the patients in question and constituting the principal service.

50 Therefore, those activities do not fall within the concept of activities 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive. Indeed, since the hospital and medical care have not been performed, commenced or yet envisaged, activities such as those at issue in the main proceedings are merely liable, if certain eventualities come to pass, to be closely related to medical care provided in a hospital environment.

51 As regards, finally, the possibility raised in the fourth question, namely the allogeneic rather than autologous use of the cord stem cells, it is sufficient to observe that that circumstance has, as a rule, no bearing on the conclusions set forth in paragraphs 34 to 50 of the present judgment.

52 Having regard to the foregoing, the reply to the first, second and fourth questions referred, read together, is that the concept of activities 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) of the Sixth Directive is to be interpreted as meaning that it does not cover activities such as those at issue in the main proceedings consisting in the collection, transportation and analysis of cord blood and the storage of stem cells contained in it, where the medical care provided in a hospital environment to which those activities are merely potentially related has not been performed, commenced or yet envisaged.

The third question, read in conjunction with the fourth question

53 The third question is intended, in essence, to ascertain whether, in circumstances such as those at issue in the main proceedings, national authorities may legitimately decide that taxable persons such as CopyGene are not 'other duly recognised establishments of a similar nature' to 'hospitals [and] centres for medical treatment or diagnosis' within the meaning of Article 13A(1)(b) of the Sixth Directive.

54 In that context, the referring court is asking in particular whether, if the services of stem cell banks such as those at issue in the main proceedings are performed by professional medical personnel, where such stem cell banks, although authorised by the competent health authorities of a Member State within the framework of Directive 2004/23 to handle human tissue and cells, do not receive any support from the public health insurance scheme and where the payment for those services is not covered by that scheme, Article 13A(1)(b) of the Sixth Directive precludes the national authorities from deciding that taxable persons such as CopyGene are not 'other duly recognised establishments of a similar nature' to 'hospitals [and] centres for medical care or diagnosis' within the meaning of Article 13A(1)(b) of the Sixth Directive.

55 The fourth question concerns, particularly, the point whether the possibility of a taxable person such as CopyGene being authorised to supply services with a view to both autologous and allogeneic uses could have any bearing on the reply to be given to the third question.

56 In the words of Article 13A(1)(b) of the Sixth Directive, Member States are to exempt from VAT the supply of services coming within that provision where those services are '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'.

57 In this respect, it should be noted that the rules for interpreting the exemptions in Article 13 of the Sixth Directive set out in paragraph 26 of the present judgment apply to the specific conditions laid down for those exemptions to apply and in particular to those concerning the status or identity of the economic agent performing the services covered by the exemption (see *Eulitz*, paragraph 42, and the case-law cited).

58 As regards Article 13A(1)(b) of the Sixth Directive, it is clear from the Court's settled case-law that that provision covers duly recognised establishments pursuing social purposes, such as the protection of human health (see, to that effect, *Dornier*, paragraph 47).

59 As regards, as a preliminary point, the concept of 'other … establishments of a similar nature' to 'hospitals [and] centres for medical treatment or diagnosis' within the meaning of Article 13A(1)(b) of the Sixth Directive, the Danish and Greek Governments maintain that CopyGene cannot be likened to hospitals or centres for medical treatment or diagnosis.

60 Where necessary, it is for the referring court to determine whether an operator such as CopyGene is 'of a similar nature' to hospitals and centres for medical treatment or diagnosis. It should be noted, as the Court has already ruled, that since diagnostic medical tests, in the light of their therapeutic purpose, come within the concept of 'medical care' as referred to in Article 13A(1)(b) of the Sixth Directive, a laboratory governed by private law and undertaking analyses must be regarded as being an establishment 'of a similar nature' to 'hospitals' and 'centres for medical treatment or diagnosis' within the meaning of that provision (see *L.u.P.*, paragraphs 18 and 35). That being so, in the present case, CopyGene, in answer to a question at the hearing before the Court, stated in essence that, usually, it analyses cord stem cells solely in order to ascertain whether there are sufficient 'viable' cells to justify the preservation of the sample in question.

61 As regards the meaning of 'duly recognised establishments', that is to say the only one of the requirements set out in paragraph 56 of the present judgment which was addressed in detail either in the decision for reference or in the observations submitted to the Court, it is clear from the case-law that the recognition of an establishment for the purposes of Article 13A(1)(b) of the Sixth Directive does not presuppose a formal recognition procedure and that such recognition need not necessarily be derived from national tax law provisions (see, to that effect, *Dornier*, paragraphs 64, 65, 67 and 76).

62 Therefore, the fact that the Kingdom of Denmark has not exercised the right, provided for by Article 13A(2)(a) of the Sixth Directive, to make the granting to bodies other than those governed by public law of the exemption provided for in Article 13A(1)(b) subject, in each individual case, to one or more of the conditions referred to later in paragraph 2, does not affect the possibility that an establishment may be

recognised for the purposes of granting the exemption referred to in Article 13A(1)(b) of the Sixth Directive (see, by analogy, *Dornier*, paragraph 66).

63 It is thus, in principle, for the national law of each Member State to lay down the rules according to which such recognition may be granted to establishments which request it. The Member States enjoy a discretion in this regard (*Dornier*, paragraphs 64 and 81, and *L.u.P.*, paragraph 42).

64 Where a taxable person seeks the status of an establishment duly recognised for the purposes of Article 13A(1)(b) of the Sixth Directive, it is for the competent authorities to observe the limits of the discretion conferred upon them by the latter provision in applying the principles of European Union law, in particular the principle of equal treatment which, in the field of VAT, takes the form of the principle of fiscal neutrality (see, to that effect, *Dornier*, paragraph 69, and *L.u.P.*, paragraph 48).

65 In that regard, in order to determine which establishments should be 'recognised' under that provision, the national authorities should, in accordance with European Union law and subject to review by the national courts, take into consideration a number of factors, which include the public interest of the activities of the taxable person in question, the fact that other taxable persons carrying on the same activities already have similar recognition, and the fact that the costs incurred for the treatment in question may be largely met by health insurance schemes or other social security bodies (see, to that effect, *Kügler*, paragraphs 57 and 58; *Dornier*, paragraphs 72 and 73; and *L.u.P.*, paragraph 53).

66 In the present case, it is common ground that the Kingdom of Denmark has not laid down any specific rules or procedure implementing Article 13A(1)(b) of the Sixth Directive which would apply to service providers which are not bodies governed by public law. Contrary to CopyGene's suggestion at the hearing, the mere fact that several other Member States have systematically exempted the services of private cord stem cell banks can have no bearing on the reply to the third question referred. As is clear from paragraphs 63 and 64 of the present judgment, the Danish authorities have a discretion in this respect, subject to complying with European Union law, including, in particular, the principle of fiscal neutrality.

67 It is apparent from the wording of the third question that the factors which the referring court considers to be of possible relevance in that regard include, in particular, the fact that, first, the services provided by CopyGene are performed by professional medical personnel, second, those services are not supported or covered by any public social security scheme and, third, CopyGene has been authorised by the competent health authorities to handle cord stem cells under the national legislation implementing Directive 2004/23.

68 As regards, first of all, the fact that CopyGene's services are supplied, within the framework of contracts concluded with it, by professional medical personnel, that is to say nurses, midwives and bioanalysts, the documents before the Court do not reveal for which activities those personnel are 'professionally qualified' under the relevant national legislation, the content of which is also not apparent from those documents. That being so, it should be pointed out that, in any event, the mere fact that they are qualified health professionals does not prevent, as such, the Danish authorities refusing to grant to a taxable person such as CopyGene the recognition which would entitle it to the exemption under Article 13A(1)(b) of the Sixth Directive.

69 As regards, next, the fact that CopyGene's activities at issue in the main proceedings receive no support from and are not covered by the public social security scheme, it is clear from the case-law cited in paragraph 65 of the present judgment that the national authorities are entitled to take that factor into consideration in order to determine whether an entity should be recognised for the purposes of Article 13A(1)(b) of the Sixth Directive.

70 That same fact is also a matter which can be taken into account in the determination, which is not the subject of this request for a preliminary ruling, of whether a taxable person supplies its services 'under social conditions comparable to those applicable to bodies governed by public law' within the meaning of that provision.

71 It should, however, be made clear that the considerations set forth in paragraphs 69 and 70 of the present judgment do not mean that the exemption under Article 13A(1)(b) of the Sixth Directive must be systematically excluded when the services supplied are not reimbursed by the social security authorities. It is rather a factor which must be weighed in the balance, and which could be outweighed, for example, by the necessity to ensure equal treatment. Indeed, it is also apparent from the case-law that, if, for example, a taxable person's situation is comparable to that of other operators providing the same services in comparable situations, the mere fact that the cost of those services is not fully covered by the social security authorities does not justify a difference in the treatment of providers for VAT purposes (see, to that effect, *Dornier*, paragraph 75).

72 Furthermore, contrary to the Greek Government's suggestion, the mere fact that a taxable person such as CopyGene is an establishment governed by private law does not automatically mean that such a taxable person's activities could not come within the exemption under Article 13A(1)(b) of the Sixth Directive. When the Community legislature intended to restrict the grant of the exemptions under Article 13A(1) of

the Sixth Directive to certain non-profit-making or non-commercial entities, it said so expressly, as is clear from subparagraphs (l), (m) and (q) thereof (see Case C-498/03 *Kingscrest Associates and Montecello* [2005] ECR I-4427, paragraph 37).

73 In addition, it is important to note that, having regard particularly to the principle of fiscal neutrality, the approach adopted by the tax authorities when they examine competing comparable establishments must be consistent. On that point, CopyGene's Counsel confirmed at the hearing that there was no other private stem cell bank in Denmark.

74 As regards, finally, the fact that CopyGene has been authorised by the competent health authorities to handle cord stem cells under the national legislation implementing Directive 2004/23, it is true that, to a certain extent, that factor tends to suggest that CopyGene carries on activities dealing with hospital and medical care. Such authorisation can therefore be a factor tending to support the argument that CopyGene is, in any case, 'duly recognised' within the meaning of Article 13A(1)(b) of the Sixth Directive.

75 However, if the national authorities are not to be deprived of the discretion which that provision confers upon them, the mere fact that they have authorised activities such as those at issue in the main proceedings, in accordance with the European Union's prescribed standards of quality and safety in the sector concerned, cannot lead, by itself and automatically, to recognition from the point of view of Article 13A(1)(b) of the Sixth Directive. As the Danish Government maintains, obtaining such authorisation is a necessary condition to carrying on the activity of a private stem cell bank. However, the granting of such authorisation is not, in itself, synonymous with recognition for the purposes of Article 13A(1)(b) of the Sixth Directive.

76 The same applies as regards the other provisions of the Danish rules on private stem cell banks cited by CopyGene, which are referred to in paragraph 13 of the present judgment.

77 It follows that Article 13A(1)(b) of the Sixth Directive does not therefore, by itself, preclude the Danish tax authorities from refusing to treat CopyGene as a 'duly recognised' establishment for the purposes of the exemption at issue in the main proceedings.

78 That said however, neither can that provision be interpreted as requiring, as such, the competent authorities to refuse to treat a taxable person such as CopyGene as an establishment 'duly recognised' for the purposes of that exemption.

79 In those circumstances, it would be for the national court, in so far as necessary, to determine whether the refusal of recognition for the purposes of the exemption provided for in Article 13A(1)(b) of the Sixth Directive complies with the requirements of the case-law set forth in paragraphs 63 to 65 of the present judgment, and in particular with the principle of fiscal neutrality. To that end, it would be appropriate to take into consideration, for example, established administrative practice and other practices adopted as regards the status of paramedical establishments and exemptions from VAT in sectors comparable to that in question in the main proceedings.

80 As regards the fourth question, it is sufficient to observe that the nature of the envisaged treatment, whether autologous or allogeneic, is irrelevant to the reply to be given to the third question.

81 In the light of the foregoing, the reply to the third and fourth questions referred, read together, is that, if the services of stem cell banks such as those at issue in the main proceedings are performed by professional medical personnel, where such stem cell banks, although authorised by the competent health authorities of a Member State, within the framework of Directive 2004/23, to handle human tissue and cells, do not receive any support from the public social security scheme and where the payment for those services is not covered by that scheme, Article 13A(1)(b) of the Sixth Directive does not preclude the national authorities from deciding that taxable persons such as CopyGene are not 'other duly recognised establishments of a similar nature' to 'hospitals [and] centres for medical care or diagnosis' within the meaning of Article 13A(1)(b) of the Sixth Directive. However, neither can that provision be interpreted as requiring, as such, the competent authorities to refuse to treat a private stem cell bank as an establishment 'duly recognised' for the purposes of the exemption in question. To the extent that it is necessary, it is for the referring court to determine whether the refusal of recognition for the purposes of the exemption provided for in Article 13A(1)(b) of the Sixth Directive complies with European Union law and, in particular, with the principle of fiscal neutrality.

Costs

82 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

1. **The concept of activities 'closely related' to 'hospital and medical care' within the meaning of Article 13A(1)(b) 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 is to be interpreted as meaning that it does not cover activities such as those at issue in the main proceedings consisting in the collection, transportation and analysis of umbilical cord blood and the storage of stem cells contained in it, where the medical care provided in a hospital environment to which those activities are merely potentially related has not been performed, commenced or yet envisaged.**

2. **If the services of stem cell banks such as those at issue in the main proceedings are performed by professional medical personnel, where such stem cell banks, although authorised by the competent health authorities of a Member State, within the framework of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells, to handle human tissue and cells, do not receive any support from the public social security scheme and where the payment for those services is not covered by that scheme, Article 13A(1)(b) of Sixth Directive 77/388 does not preclude the national authorities from deciding that taxable persons such as CopyGene A/S are not 'other duly recognised establishments of a similar nature' to 'hospitals [and] centres for medical care or diagnosis' within the meaning of Article 13A(1)(b) of Sixth Directive 77/388. However, neither can that provision be interpreted as requiring, as such, the competent authorities to refuse to treat a private stem cell bank as an establishment 'duly recognised' for the purposes of the exemption in question. To the extent that it is necessary, it is for**

the referring court to determine whether the refusal of recognition for the purposes of the exemption provided for in Article 13A(1)(b) of Sixth Directive 77/388 complies with European Union law and, in particular, with the principle of fiscal neutrality.

[Signatures]