OPINION OF ADVOCATE GENERAL

Sharpston

delivered on 10 September 2009 (1)

Case C?262/08

CopyGene A/S

v

Skatteministeriet

(Reference for a preliminary ruling from the Østre Landsret (Denmark))

(VAT – Exemptions – Activities closely related to hospital and medical care undertaken by duly recognised establishments of a nature similar to hospitals or centres for medical treatment or diagnosis – Collection, transportation, analysis and storage of umbilical cord blood)

1. Community VAT rules provide for the exemption of, inter alia, hospital and medical care and ‘closely related activities’ undertaken by bodies governed by public law or, under comparable social conditions, by hospitals, centres for medical treatment or diagnosis or ‘other duly recognised establishments of a similar nature’.

2. In this reference for a preliminary ruling, the Østre Landsret (Eastern Regional Court), Denmark, seeks to ascertain whether that exemption may cover the collection, transportation, analysis and storage of umbilical cord blood for possible future therapeutic use, when those services are supplied by a private stem cell bank which is officially authorised to handle stem cells from such blood.

Relevant Community legislation

VAT legislation

3. The main proceedings concern services provided before 2007, so that the relevant Community VAT legislation is the Sixth Directive. (2)

4. Article 13A(1) of that 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;

(d) supplies of human organs, blood and milk;

…' (3)

5. Under Article 13A(2)(a), for bodies not governed by public law, Member States may make the granting of each exemption provided for in, inter alia, Article 13A(1)(b) subject to one or more of four conditions – in substance that such bodies should be essentially non-profitmaking and/or run on an essentially voluntary basis and/or should charge prices approved by the public authorities or at least lower than those charged for similar services by commercial enterprises subject to VAT and/or that there should be no likelihood of distortion of competition vis-à-vis such enterprises.

6. Under the first indent of Article 13A(2)(b), supplies of goods or services are not to be granted exemption under, inter alia, Article 13A(1)(b) if they are 'not essential to the transactions exempted'. (4)

The Tissues and Cells Directive

7. Standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells are laid down in the Tissues and Cells Directive, (5) Article 1 of which states that it concerns tissues and cells 'intended for human applications, in order to ensure a high level of protection of human health'. The preamble to the directive explains, moreover, 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 1) and refers extensively to the medical and therapeutic uses with which the directive is concerned. Recital 7 indicates that the directive should apply to umbilical cord stem cells.

8. Article 6(1) of the Tissues and Cells Directive provides:

'Member States shall 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.'

Facts, procedure and questions referred

9. The order for reference 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, umbilical cord blood, bone marrow or peripheral (that is to say, circulating) blood, and used to treat diseases in which special cells are absent or have been destroyed. However, not all kinds of stem cell can be used to treat all types of disease; in some cases, stem cells from umbilical cord blood ('cord stem cells') are preferable.

10. CopyGene A/S ('CopyGene'), Scandinavia's largest private stem cell bank, offers parents a service of collecting, transporting, analysing and storing umbilical cord blood so that cord stem cells may be used to treat their child in the possible event of certain subsequent serious diseases. Those services are not covered or reimbursed in any way by the Danish public health insurance scheme.

11. 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 health personnel who have also signed a contract with CopyGene. It is then taken to CopyGene's laboratory and analysed to establish whether there are sufficient live stem cells to justify storage. If there are, the parents can sign a further renewable contract with CopyGene, for cryopreservation (freezing) and storage.

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

13. The order for reference states that cord stem cells have been used since 1988 inter alia to treat and cure cancer and that, in the long term, it is expected that they will be used to treat yet more diseases. Whether they are intended for autologous or allogeneic use, (6) such cells are collected at the time of delivery and in the great majority of cases will be frozen for an indeterminate period until such time as the need to use them for therapeutic purposes may arise.

14. The order for reference also points out that, in its opinion of 16 March 2004 on the ethical aspects of umbilical cord blood banking, (7) the European Group on Ethics in Science and New Technologies ('the EGE') stated inter alia that 'the likelihood that the sample may be used to treat one's child is currently negligible, that the future therapeutic possibilities are of a very hypothetical nature and that up until now there is no indication that the present research will lead to specific therapeutic applications of one's own cord blood cells' – but that other more recent scientific papers suggest that future possibilities are more real and more significant.

15. Under Danish legislation implementing the Tissues and Cells Directive, CopyGene has been authorised to handle cord stem cells for autologous use. It has also purchased another Danish stem cell bank which is authorised to handle stem cells for both autologous and allogeneic use. Consequently, CopyGene now looks after 2 000 stem cell samples for autologous use which it has collected and 1 000 samples for both autologous and allogeneic use which were collected by the other bank. CopyGene's activities are regulated by, inter alia, Danish health ministry guidelines on biobanks in the health sector.

16. That is, essentially, the context in which CopyGene maintains that the services in issue should be exempt from VAT, as activities closely related to hospital and medical care undertaken by duly recognised establishments of a nature similar to hospitals or centres for medical treatment or diagnosis. The Skatteministeriet (Tax Ministry) considers that the services should be taxed.

17. The Østre Landsret therefore seeks a preliminary ruling on the following questions:

'(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 [the Tissues and Cells Directive]?

(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 [the Tissues and Cells Directive]?’

18. Written and oral observations have been submitted by CopyGene, the Danish and Greek Governments and the Commission.

Assessment

Preliminary remarks

19. Both the order for reference and the observations to the Court mention scientific and ethical issues relating to cord stem cell banking, in particular private banking for autologous use. It appears to be an area which is not entirely uncontroversial.

20. Scientific reservations concern, inter alia: uncertainty as to the quality of stem cells after lengthy periods of cryopreservation; the low volume of cells collected on each occasion; lower success rates than with bone marrow stem cells; and the low number of transplantations of cord stem cells that have actually been carried out to treat a limited number of conditions. However, progress is constantly being made and such reservations are often less strongly and less widely expressed than before; moreover, the collection of cord stem cells is simpler and less invasive than that of bone marrow stem cells, and they are more suitable for certain types of treatment. On

another level, banking for autologous treatment may be less useful than for allogeneic treatment, as stem cells from a child's own umbilical cord blood are limited in number and cannot be used to treat genetic diseases. (8)

21. Ethical issues concern, inter alia: the possibility that collection of cord blood might interfere with delivery and endanger the welfare of child or mother; the risk that parents might be persuaded to pay for ultimately redundant services on the basis of exaggerated claims; the merits of publicly funded banks storing altruistically donated stem cells for allogeneic treatment as against private banks charging to store cells for treatment of the donor or his family; the unacceptability of ruling out any life-saving possibility; and the need to ensure that stem cell availability does not vary according to ethnic grouping.

22. I do not claim thereby to provide a complete and balanced picture, accurate in detail – my intention is to give no more than a rough sketch of some of the types of concern raised. (9) And I express no view whatever on those concerns.

23. In particular, I am in no position to evaluate the current state of scientific knowledge concerning the likely usefulness of cord stem cell storage for either autologous or allogeneic treatment.

24. Nor do I think the Court is in such a position, particularly since 'the current state of scientific knowledge' is constantly, often rapidly, evolving. More importantly, it is not the Court's role in a preliminary ruling procedure to determine factual matters of that nature – and the referring court itself, whose task it is to decide such issues, does not express any definitive position on the validity of the competing views.

25. Consequently, I would not accept the suggestion, made particularly clearly by the Commission, that the Court's interpretation of the Sixth Directive should be based explicitly or implicitly on the current state of scientific knowledge.

26. However, one fact stated by the referring court and accepted by both CopyGene and the Danish authorities is that the use of cord stem cells for transplantation dates, essentially, from 1988. (10) That may be relevant when we bear in mind that the list of exemptions in Article 13 of the Sixth Directive (11) is in some ways a fossil from an earlier age – it was adopted in a social, economic and scientific context now some four decades old and has never been substantively amended. It may therefore be appropriate, when interpreting the wording of the exemption, to take account of situations which were not envisaged in 1977 – in terms of both medical progress and changing approaches to healthcare in the intervening years.

Structure of Article 13A(1)(b)

27. When examining the questions referred, it seems to me important to have a clear idea of the structure of Article 13A(1)(b) of the Sixth Directive, which may, in my view, be represented as follows:

There is exemption from VAT under Article 13A(1)(b) of the Sixth Directive if

the service provided

AND

the service provider

is hospital or medical care

OR

is an activity closely related to hospital or medical care

is a body governed by public law

OR

provides the service under social conditions comparable to those applicable to bodies governed by public law

AND

is a hospital or centre for medical treatment or diagnosis

OR

is an establishment of a similar nature

AND

is duly recognised

28. The definition of ‘closely related activities’ is at issue in questions 1, 2 and 4 in the present case, and that of ‘duly recognised establishments of a similar nature’ in questions 3 and 4.

29. It seems to me preferable to approach those issues in the light of the structure of the provision rather than the strict framework of the questions referred. I shall consider the characteristics of, first, the services concerned (questions 1, 2 and 4) and, second, the service provider (questions 3 and 4), whilst endeavouring to address all the issues on which the national court seeks guidance.

Characteristics of the services (questions 1, 2 and 4)

The Court’s case-law

30. The Court has consistently stated that the exemptions in Article 13 of the Sixth Directive are independent concepts of Community law. The terms used are to be interpreted strictly, as exceptions to the general principle that VAT is to be levied on all supplies for consideration. However, that does not mean that they should be construed in such a way as to deprive them of their intended effect. They must be interpreted in context and in the light of the scheme of the

directive, having particular regard to the underlying purpose of each exemption. Moreover, Article 13A does not exempt all activities in the public interest, only those which are listed and described in detail. (12)

31. A number of those exemptions concern supplies or activities which are incidental, or closely linked or related, to a principal supply which is exempted in the public interest. More generally, the Court has considered that services which are ancillary to a principal service should share the tax treatment of that principal service. In both contexts, it considers that an incidental, linked, related or ancillary supply is one which does not constitute for customers an aim in itself, but a means of better enjoying the principal service supplied. (13) However, a supply which is not essential to attain the objective of the principal service, even though it may be regarded as of great assistance to that service, will not be regarded as closely related. (14)

32. As regards more particularly activities closely related to hospital and medical care, the case-law provides a number of further indications.

33. First of all, the exemptions in Article 13A(1)(b) and (c) both have the objective of reducing the cost of healthcare. The term ‘medical care’ must be interpreted in the same way in both, as they are intended to regulate all exemptions of medical services in the strict sense: those which have as their purpose the diagnosis, treatment and, in so far as possible, cure of diseases or health disorders. (15) The purpose of a medical service determines whether it should be exempt; if the context shows that its principal purpose is not the protection, maintenance or restoration of health but some other aim, the exemption does not apply. (16)

34. Services are closely related to hospital or medical care only if they are actually supplied as an ancillary to such care provided to patients as a principal service, only if they are logically part of the provision of that care, and only if they constitute an indispensable stage in the process of providing that care to achieve its therapeutic objectives, because only such services are of a nature to influence the cost of healthcare which is made accessible by the exemption. (17)

35. However, the notion of therapeutic purpose should not be understood too narrowly. Preventive medical services may be exempt under Article 13A(1)(c). It is consistent with the aim of reducing healthcare costs to include examinations or preventive medical treatment within the ‘provision of medical care’, even when the persons concerned are clearly not suffering from any disease or health disorder. (18)

36. Activities which have been held to constitute medical care include: therapeutic care as part of an out-patient service provided by qualified nursing staff; (19) psychotherapeutic treatment given by qualified psychologists; (20) conducting medical examinations, or taking blood or other samples to test for the presence of disease, on behalf of employers or insurers, or certifying medical fitness to travel, where such services are intended principally to protect the health of the person concerned; (21) and medical tests which allow patients to be observed and examined before it becomes necessary to diagnose, care for or heal a potential illness, prescribed by general practitioners and carried out by an outside private laboratory. (22)

37. Among services which have been held *not* to constitute medical care are: a genetic test carried out by a doctor to establish paternity; (23) general care and domestic help provided as part of an out-patient service; (24) and a doctor’s report on a person’s state of health for the purposes of a war or disability pension claim or of personal injury litigation. (25)

38. There are fewer instances in the case-law of supplies which have been held to be, or not to be, ‘closely related activities’ where the principal service is hospital or medical care covered by Article 13A(1)(b).

39. On the one hand, the Court has considered that, where an authorised healthcare worker prescribes an analysis for the purpose of diagnosis and with a therapeutic aim, the transmission of the patient’s sample, which logically takes place between the taking of the sample and the analysis itself, is closely related to the analysis and therefore exempt from VAT. (26)

40. On the other hand, if a hospital or other body covered by Article 13A(1)(b) supplies telephone services or hires out televisions to in-patients, or supplies beds or meals to people accompanying them, those are not activities closely related to hospital and medical care unless (i) they are essential to achieve the therapeutic objectives of the care and (ii) their basic purpose is not to obtain additional income by carrying out transactions in direct competition with those of commercial enterprises liable for VAT. (27)

Application to the present case

– Question 1

41. First of all, neither the referring court nor any of those submitting observations has suggested that the services in issue can be classed as VAT-exempt medical care in themselves.

42. That appears to be the correct approach. It is clear from the order for reference that the collection, transport, analysis and storage of cord stem cells in the manner practised by CopyGene does not have as its direct purpose any actual diagnosis, treatment or cure of diseases or health disorders, or any actual protection, maintenance or restoration of health.

43. However, that does not necessarily rule out the possibility that in other circumstances the collection and analysis (and any related transport and storage) of umbilical cord blood may have a diagnostic purpose of a kind which has been accepted by the Court as falling within the concept of medical care. At the hearing, counsel for CopyGene indicated that, where there is a known hereditary disease in the donor’s family, the sample may be screened for the presence of that disease. That is, of course, a matter for the national court to determine – as is the question whether the screening has any true diagnostic purpose, as opposed to merely forming part of the testing for viability of the cells.

44. The essential question is therefore whether the services at issue may be ‘closely related’ to hospital or medical care.

45. It is explicitly stated in the order for reference that the stem cells covered by those services may be used only for hospital care, to the exclusion of research. (28) Furthermore, it is clear from the literature that, while particular treatments may vary, the medical use of stem cells, including cord stem cells, systematically involves transplantation with a view to replacing cells which are in some way defective. There can be no doubt that such use falls within the notion of treatment or cure of diseases or health disorders, or restoration of health, and there seems little likelihood that it will be carried out anywhere but in a hospital.

46. A clear parallel can be drawn with blood transfusion or organ transplantation. It is true that supplies of human blood and organs are covered by another specific exemption, in Article 13A(1)(d) of the Sixth Directive. One might therefore argue that such supplies are in a category

other than activities closely related to hospital or medical care. One might also infer from the non-inclusion of supplies of human tissues and cells that such supplies had been intentionally excluded from exemption.

47. However, if Article 13A(1)(d) had been absent, I do not think it conceivable that the Court would have considered the collection, transport, analysis or storage of blood for transfusion or of organs for transplantation to be anything other than closely related to hospital or medical care.

48. Moreover, the list of exemptions in Article 13 of the Sixth Directive was adopted some four decades ago. (29) It is not implausible that, if the use of human cells for therapeutic purposes had been as well established in the 1970s as were organ transplants and blood transfusion, supplies of cells would have been mentioned in Article 13A(1)(d).

49. Thus, in my view, when specific human cells, including cord stem cells, are collected, transported, analysed and stored for a purpose which cannot be other than the treatment or cure of diseases or health disorders, or the restoration of health, the services concerned must be closely related to the hospital or medical care which seeks to achieve that aim. When cells are used for such a purpose, they are logically part of the provision of the care in question.

50. The national court refers to a possible ‘temporal requirement’. However, it does not seem to me possible to consider that the length of time which elapses between the collection and the medical use of such cells can influence the assessment. Clearly, the length of time may vary – for blood, organs, stem cells or other tissue – and is dependent largely on the frequency of an opportunity for use, on the degree of compatibility between donor and recipient and on the preservability of the material concerned. However, any limit imposed could only be arbitrary.

51. It may be necessary, in law, to impose arbitrary limits – time-limits, age-limits or speed-limits, for example – but they are a matter for the legislature and not for the judiciary. (30) Nor does there appear to be anything in the context or underlying aim of the exemption for services closely related to hospital or medical care, or in the scheme of the Sixth Directive, which requires an arbitrary distinction to be drawn, on grounds of elapsed time alone, between services which are closely related to hospital or medical care and those which are not.

52. Consequently, when human tissue or cells are collected, transported, analysed and stored for purposes which cannot be other than those of hospital or medical care, the fact that those services are closely related to the care in issue cannot, in my view, be called into question by the mere fact that some considerable time may elapse before the material is actually used for those purposes. That would be so in any event, but must be all the more true when it is materially impossible to collect the blood containing the stem cells other than at the time of birth.

53. In particular, the national court asks whether the hospital care to which the service is closely related must exist or be specifically performed, commenced or envisaged, in order for the exemption to apply.

54. Whilst it is true that the Court has considered services to be closely related to hospital or medical care only if they are ‘actually’ supplied as an ancillary to such care, (31) I would suggest that a situation in which services are actually supplied and can serve no other purpose than as a necessary ancillary to hospital or medical care meets that requirement.

55. When, for example, blood is taken from a donor for transfusion, it may be intended in certain cases for a specific recipient in the context of a specific existing, commenced or envisaged treatment, but most blood donations are intended for as yet unknown emergencies. I see no reason why the difference between the two situations should lead to different VAT treatment,

whether in the case of blood or of any other tissue or cell transplant for the purposes of hospital or medical care.

56. The final dimension to the national court's first question is whether the uncertainty as to whether there will ever be any actual use of the stem cells for hospital or medical care can influence the VAT treatment of the services concerned.

57. Again, I can see no reason why it should make any difference. It is in the nature of blood, organs, tissue or cells collected for the purpose of medical treatment that some samples will never be used, for a variety of reasons. It seems to me that what matters is that the services should have been provided with a therapeutic aim in mind and cannot be diverted to any other purpose. That, according to the order for reference, appears to be the situation as regards the services in issue in the main proceedings. Moreover, whenever the principal service (medical treatment using cord stem cells) is supplied, the link between it and the ancillary service is in no way uncertain.

58. A comparison might be made here with the Court's case-law to the effect that taxed inputs which are intended to be used for taxable output transactions still give rise to a right to deduct even if those latter transactions never in fact take place. (32) Even if exemption and deduction are different concepts, it is clear that Community law does not make VAT treatment necessarily dependent on ultimate use as a general rule.

59. Other points have been raised by the Danish and Greek Governments and the Commission: first, whether the services in issue should be excluded from the exemption because they are not essential to the exempted hospital or medical care; second, whether they should be excluded because exemption would not reduce the cost of healthcare; and, third, whether they should be excluded because they are not prescribed by a doctor or other authorised healthcare worker.

60. It is true that, under Article 13A(2)(b) of the Sixth Directive, supplies are not to be exempted under Article 13A(1)(b) if they are not essential to the transactions exempted, and that the Court has held that services are not to be regarded as essential if they are merely 'of great assistance' in attaining the objective of the principal exempt supply. (33) However, it seems clear to me that, if stem cell therapy is performed, the availability of stem cells must be regarded as essential to that therapy, and not merely of great assistance. Nor can it matter that other sources of stem cells (from bone marrow or from peripheral blood, or from a different donor) may be available; it cannot be the case that the mere existence of alternatives systematically rules out exemption. Moreover, the referring court specifically states that bone marrow and peripheral blood stem cells cannot be used for certain types of disorder. I therefore consider that there is no reason to rule out exemption on the basis of Article 13A(2)(b).

61. It is also true that the Court has consistently stressed that the exemptions in Article 13A(1)(b) and (c) of the Sixth Directive have the aim of reducing healthcare costs. The Danish and Greek Governments argue that exemption of the services in issue here would not reduce those costs, essentially because they are not related to actual treatment. However, it seems to me that, to the extent that cord stem cells can be used in medical care (and it is common ground that they can), then the cost of that care will be reduced by exempting the preparatory services required to make those cells available from VAT. Moreover, I would suggest that, while the reduction of healthcare costs is indeed the aim of the exemption, exemption does not depend on achieving such a reduction in the case of each individual supply.

62. The Danish Government draws attention to the fact that CopyGene's services are not prescribed by any doctor or healthcare professional, in contrast to the situation in *Commission* v *France*, where the Court stressed the fact that the analysis was ordered by a duly authorised

healthcare worker. However, that comparison does not seem entirely in point. The principal service in that case was the analysis, which fell within the notion of medical care; the ‘closely related activity’ was the transmission of the sample, a service not itself specifically ordered by a healthcare worker but forming a necessary adjunct to the analysis. In the present case, it does not seem possible to doubt that the medical care which forms the principal service and the only purpose for which CopyGene’s services can be used will be provided only if ordered or approved (and, indeed, almost certainly carried out) by a medical practitioner.

63. I therefore reach the view that services of the kind described do constitute activities closely related to hospital or medical care within the meaning of Article 13A(1)(b) of the Sixth Directive.

– Question 2

64. The national court asks whether Article 13A(1)(b) covers general preventive services supplied before the hospital or medical care is required. In my view, the answer may be brief.

65. It is clear from the case-law that preventive services may benefit from the exemptions in Article 13A(1)(b) and (c), and that they even form part of hospital or medical care itself, rather than being merely closely related activities. (34)

66. That, however, does not appear to be of any particular relevance here. I agree with the view apparently expressed by the Skatteministeriet in the main proceedings – the services in issue do not appear, from the description given, to have any preventive aim. In the normal meaning of the concept, preventive medical services are those which serve to avert, avoid or prevent disease, injury or health problems, or to detect latent or incipient conditions so that early treatment may be provided. The services provided by CopyGene, however, seek to ensure that a particular resource will be available for treatment if treatment becomes necessary. They do not seek in any way to avert, avoid or prevent the occurrence of a health disorder, or to detect such a disorder in a latent or incipient state. Even if such detection may be another possible purpose of collecting cord stem cells, the order for reference indicates that it is not CopyGene’s purpose with regard to the services in issue. (35)

67. CopyGene argues that, if cord stem cells are collected at birth and stored, they can be used as soon as a relevant disease is detected, thus helping to prevent the disease from progressing to a more serious or even lethal stage. However, that, it seems to me, is to confuse the principal and ancillary services. The treatment for which the cells are used may be of a preventive or curative nature, but that does not affect the nature of the collection, transportation, analysis and storage of the cells. Those activities do not in themselves have any features of prevention.

– Question 4

68. The national court wishes to know, essentially, whether the classification of the services concerned is affected if the use envisaged for the cord stem cells in question is allogeneic rather than autologous.

69. It seems to me that the difference between those types of use will affect only the likelihood that the stem cells in question will be used. The Commission and the Danish Government in particular stress the extremely low likelihood of cord stem cells ever being used in autologous treatment. That likelihood will necessarily be higher in the case of allogeneic use, since the number of potential recipients may be very large – a factor which would also reduce the average

time lapse between collection and use. Even in cases where the intended use is confined to a family group, there may be several possible recipients, whereas autologous use concerns, by definition, only a single recipient.

70. However, if, as I consider, the precise degree of probability of use is not relevant, as long as the services in issue are provided with a therapeutic aim in mind and cannot be diverted to any other purpose, (36) the distinction between autologous and allogeneic use will not be relevant either. I would merely say that, if – and I do not suggest that such is the case here – the known likelihood of (in particular, autologous) use were so vanishingly small as to lead the national court to the conclusion that the purpose of the services in question could not reasonably be regarded as being to make cells available for possible medical treatment but rather to make money by exploiting parents' fears and hopes, then of course those services could not be described as closely related to hospital or medical care.

71. With regard to possible classification as preventive medical services, both autologous and allogeneic uses of cord stem cells clearly themselves constitute medical care within the meaning of the Sixth Directive. Consequently, provided that an ancillary service is 'closely related' to such care, the precise nature of the care will not affect the assessment of the service as preventive or otherwise.

Characteristics of the service provider (questions 3 and 4)

The Court's case-law

72. In *Dornier*, the Court was asked, essentially, whether the term 'other duly recognised establishments of a similar nature' presupposes a formal recognition procedure or whether recognition may also derive from the fact that the social security authorities assume the cost of treatment and, conversely, whether the fact that those authorities do not assume the cost justifies exclusion from the exemption. (37)

73. The Court pointed out, first, that Article 13A(1)(b) of the Sixth Directive does not specify any conditions or procedures for recognition. It is thus in principle for each Member State to lay down the relevant rules. In accordance with Article 13A(2)(a), for bodies not governed by public law, Member States may subject exemption under Article 13A(1)(b) to one or more of a number of specified conditions. However, there is no requirement to do so, and an establishment may be recognised even where a Member State has not exercised that option. Nor does anything in the Sixth Directive require recognition to be granted in accordance with a formal procedure or to be provided for expressly in national tax provisions. (38)

74. The Court went on to adopt a number of points which it had made in *Kügler*, with regard to recognition as a charitable organisation for the purpose of Article 13A(1)(g) of the Sixth Directive. (39) In particular, when determining which organisations should be recognised, national authorities should take a number of factors into consideration, including: the public interest of the activities of the taxable person; whether other taxable persons carrying on the same activities already have similar recognition; and the extent to which the costs are met by health insurance schemes or other social security bodies. When assessing those factors, the authorities must exercise their discretion within the limits imposed by Community law, in particular the principle of equal treatment. 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. Where recognition has not been granted, it is for the national court to

determine, in the light of all the relevant facts, whether a taxable person must none the less be regarded as ‘duly recognised’ within the meaning of that provision. (40)

75. That analysis, I note, does not explicitly examine all three prongs of the condition laid down in Article 13A(1)(b) of the Sixth Directive – namely, that the service must be provided under social conditions comparable to those applicable to bodies governed by public law *and* that the establishment must be of a similar nature to a hospital or centre for medical treatment or diagnosis *and* must be ‘duly recognised’. (41) Of course, the ‘similar nature’ of the out-patient facility in that case was not in issue. However, it is not entirely clear whether the Court was viewing social security involvement as a form of recognition or as an indication that the service was provided under comparable social conditions.

Application to the present case

76. In question 3, the national court seeks guidance on whether CopyGene can be considered a duly recognised establishment of a similar nature to a hospital or centre for medical treatment or diagnosis. The facts which it regards as possibly relevant to that determination are (i) that CopyGene’s services are performed by professional health personnel such as nurses, midwives and bioanalysts, (ii) that those services are in no way supported or covered by the public health insurance scheme, and (iii) that CopyGene is authorised by the competent health authorities to handle cord stem cells, pursuant to national legislation implementing the Tissues and Cells Directive. In question 4, it asks essentially whether the determination is affected by the fact that the services are supplied with a view to autologous or to allogeneic use.

77. I note that Denmark has not laid down any specific rules or procedure implementing Article 13A(1)(b) of the Sixth Directive for service providers who are not bodies governed by public law. (42) The Danish tax authorities therefore enjoy a degree of discretion, which must none the less be exercised in accordance with Community law. In that regard, it is not in my view significant that, as counsel for CopyGene stated at the hearing, several other Member States systematically exempt the services of private cord stem cell banks.

78. However, it appears from the order for reference and the observations of the Danish Government that the tax authorities have established an administrative practice according to which healthcare services are to be exempted if they are supplied by authorised medical personnel acting within the scope of their authorisation or if the treatment is eligible for reimbursement under the public health insurance scheme. In other cases, exemption may be granted if the treatment follows referral from a doctor or a hospital. Presumably, services which meet none of those criteria are not exempted.

79. Assuming that the Danish authorities’ decision not to grant recognition to CopyGene is compliant with their own established practice, the question is therefore *whether Community law*, which does not specify any positive criteria on which recognition must be granted, *in any way precludes the application of that practice in this case*.

80. I shall examine in that light the various factors referred to in the case-law and in the referring court’s question. In doing so, I shall follow the three-pronged structure which, on my understanding, is inherent in the condition.

– Social conditions comparable to those applicable to bodies governed by public law

81. Neither the order for reference nor any of the observations submitted explicitly mention this condition, the meaning of which is, moreover, not entirely clear.

82. It was not contained in the original proposal for the Sixth Directive, which would have exempted ‘the supply of hospital and medical services, and supplies of goods incidental thereto, by medical establishments run by: (i) bodies governed by public law; or (ii) non-profitmaking organisations; or (iii) private charitable organisations’. (43) There is, as far as I am aware, no documented reason for the inclusion of the ‘comparable social conditions’ criterion in the directive as finally adopted. (44)

83. In 1983, in its First Report on the Sixth Directive, (45) however, the Commission stated that there was difficulty in drawing the line between establishments which supply their services under social conditions comparable to those applicable to bodies governed by public law and other establishments, and that the VAT Committee’s discussions on the point had not brought things any further forward.

84. The 1984 proposal for a 19th directive (46) would have removed the words ‘by bodies governed by public law or, under social conditions comparable to those applicable to bodies governed by public law’ entirely from Article 13A(1)(b), so that the exemption would have applied to hospital and medical care and closely related activities undertaken by all hospitals, centres for medical treatment or diagnosis and other duly recognised establishments of a similar nature. However, that proposal was never adopted, and was finally withdrawn in 1993.

85. It is conceivable that the intention was to exclude from the exemption activities undertaken by private bodies run entirely on a commercial for-profit basis, which are in no way integrated into or covered by any public health service or health insurance scheme. However, not only is that a conjecture which has not been discussed in the present proceedings, but it may also be appropriate to take account of the (varying) extent to which the funding of healthcare may have shifted from public to private health insurance since 1977. (47)

86. Be that as it may, the fact that an operator’s services are not supported or covered by the public health insurance scheme is a factor which the Court has considered to be relevant. The Danish authorities’ practice therefore seems legitimate in that respect, and there appears to be no reason to cast doubt on its application in this case. That does not, however, mean that exemption must be ruled out whenever services are not reimbursed by the social security authorities; rather, it is a factor to be weighed in the balance, and may be outweighed by, for example, the need to ensure equal treatment. (48)

87. Another aspect of this condition might be, in the present case, the concerns voiced by the Danish Government (49) relating to the social desirability of public stem cell banking, with altruistic donations, as opposed to private banking, limited to individual or family interests. If such concerns are given concrete form as criteria applied in systematic administrative practice, they too may in my view form a legitimate basis for a refusal to grant exemption under Article 13A(1)(b) of the Sixth Directive.

88. Both those aspects, it may be pointed out, also fall within the notion of the public interest of the activities of the taxable person in question, which the Court considered in *Dornier* (50) to be a factor to be taken into consideration.

– Establishment of a similar nature

89. This is another aspect whose relevance has not been fully addressed in the observations, but the Greek Government has touched on it in its submission that ‘duly recognised’ means ‘duly recognised by the health authorities as an establishment similar to a hospital or centre for medical treatment or diagnosis’.

90. Whether that is so or not, the fact remains that an establishment must display the similarity in question in order to qualify for exemption.

91. Clearly, the final determination belongs to the national court, but it seems from the order for reference and from the observations of CopyGene and the Danish Government that a private stem cell bank does not share with hospitals or centres for medical treatment the – in my view defining – feature of receiving patients for the purpose of providing surgical and/or medical treatment and/or care. A stem cell bank may appear more similar to a centre for diagnosis, which does not necessarily receive patients and whose activities may include testing cells for viability, an activity which is also carried out by CopyGene. However, it appears from the case-file that, at least in its capacity as a stem cell bank, CopyGene carries out no diagnostic activity (by which I understand an activity seeking to ascertain the presence or absence, or degree of severity, of a health disorder) and, if that is so, I consider it cannot easily be regarded as similar to a centre for diagnosis. (51)

– Duly recognised establishment

92. The main focus of question 3 is whether certain factors (the employment of professional health personnel, the absence of public health insurance cover and the authorisation to handle cord stem cells) necessarily imply – together or separately – that CopyGene must (or must not) be regarded by the national court as ‘duly recognised’ for the purposes of Article 13A(1)(b) of the Sixth Directive.

93. First, in that regard, it is clear from the case-law that some principal services carried out by medical personnel may fall outside the definition of ‘medical care’ for the purposes of that provision. (52) There can thus be no reason to suppose that the use of such personnel to carry out ‘closely related’ services must lead to automatic recognition of the establishment employing them. It therefore seems to me that the Danish authorities may legitimately apply a criterion based on whether services are provided by *authorised* medical personnel *acting within the scope of their authorisation*. Consequently, provided that the criterion is applied consistently and that CopyGene’s ‘professional health personnel’ do not meet it when performing the services in question, then the mere fact that they are qualified health professionals does not preclude the Danish authorities from refusing CopyGene recognition for the purposes of the exemption.

94. Next, I have already noted (53) that the fact that an operator’s services are not (fully) reimbursed by the social security authorities is a factor which the Court stated in *Dornier* to be relevant. In the context of the condition relating to ‘comparable social conditions’, I took the view that it was a factor which could justify refusal of the exemption. I cannot reach any other view when examining it from the standpoint of due recognition.

95. On a normal reading of Article 13A(1)(b) of the Sixth Directive, a ‘duly recognised’ establishment would appear to be one which has been recognised for the purpose of the

exemption. Where, as in this case, there is no mechanism prescribed by national law for such recognition in a specific VAT context, other provisions of law should be examined – as the Court ruled in *Dornier*, recognition need not derive from national tax law provisions. Consequently, an establishment the cost of whose services is covered by public health insurance may well be considered to be 'duly recognised' – with the corollary that it is legitimate to consider one whose services are not covered not to be so recognised.

96. There remains the question of CopyGene's authorisation to handle cord stem cells, pursuant to national legislation implementing the Tissues and Cells Directive.

97. Does such authorisation, granted for the purposes of that directive, mean that the establishment concerned must be regarded as 'duly recognised' for the purposes of the Sixth VAT Directive?

98. I do not think it can have such an automatic effect, although it is certainly a factor which supports the case for recognition.

99. Given the general wording of the Sixth VAT Directive and the evolving nature of medical science, it is reasonable to consider that the definitions of medical care and closely related activities are not static but should be interpreted dynamically. (54) Such interpretation cannot be based on arbitrary criteria but rather should recognise contextual changes which may have occurred.

100. The point of accreditation, designation, authorisation or licensing pursuant to Article 6 of the Tissues and Cells Directive is to ensure that the testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are carried out in accordance with specified standards of quality and safety. The human applications in question (55) are very largely of the nature of medical care, exempt from VAT by virtue of Article 13A(1)(b) or (c) of the Sixth VAT Directive. To the extent that that is so, it would seem reasonable to consider that an establishment authorised to carry out the ancillary activities of testing, processing, preservation, storage and distribution of tissues and cells should be regarded as duly recognised for the purposes of Article 13A(1)(b).

101. The Tissues and Cells Directive was adopted in the light of innovations and developments in medical science, which must have some impact on the notion of medical care, and therefore on any definition of the term. In that context, the fact that CopyGene's services are authorised and regulated pursuant to the Tissues and Cells Directive implies that it is carrying out medically related activities, as described in the preamble to that directive.

102. However, that alone is, in my view, not enough to confer 'duly recognised' status as an automatic and mandatory result. It is clear that Member States enjoy a considerable degree of discretion in their recognition of establishments for the purposes of Article 13A(1)(b) of the Sixth Directive, and it is therefore not appropriate to conclude that recognition under the Tissues and Cells Directive must invariably lead to recognition for VAT purposes. What is important is that the tax authorities' approach should be consistent when dealing with comparable and competing establishments.

103. In that regard, counsel for CopyGene confirmed at the hearing that there are no other private stem cell banks in Denmark. Consequently, there can be no question of CopyGene's having been discriminated against because some other establishment undertaking comparable activities has been treated as 'duly recognised' for the purposes of the exemption. However, if other operators providing the same services in comparable situations had been 'duly recognised' by those authorities, the prohibition of discrimination under Community law would, in principle, have

required that CopyGene be accorded the same recognition.

104. Consequently, I am of the view that CopyGene's authorisation under the national rules implementing the Tissues and Cells Directive does not, automatically and of itself, preclude the Danish tax authorities from refusing to regard it as duly recognised for the purposes of Article 13A(1)(b) of the Sixth Directive.

– Conclusion on question 3

105. Thus, I reach the view that nothing in the Court's case-law or in the factors mentioned by the referring court – whether viewed in isolation or in combination – specifically precludes the Danish tax authorities' from deciding not to regard CopyGene as 'duly recognised' for the purposes of the exemption in question. Nor, however, is such a decision specifically required by any of those factors – although the criteria of 'comparable social conditions' and 'similar nature' may call for further examination.

106. In those circumstances, the final analysis must be for the national court itself. It must determine the weight to be accorded to each of the relevant factors, and verify that the refusal of recognition is consistent with the administrative practice laid down and with other practices adopted in comparable fields with regard, in particular, to the status of paramedical establishments and to VAT exemptions.

– Question 4

107. The nature of the intended treatment – autologous or allogeneic – should not, in my view, affect the answer to question 3. It has no bearing on the similarity of an establishment to a hospital or centre for medical treatment or diagnosis, or on its status as 'duly recognised' or not. However, I appreciate that the point is not unrelated to the concerns relating to the desirability of public rather than private stem cell banking, which I have considered above, (56) and may therefore be a factor to be weighed in the balance when considering whether the services are provided under social conditions comparable to those applicable to bodies governed by public law.

Final remark

108. In my analysis of this case, I have essentially assumed CopyGene's services of collection, transportation, analysis and storage of umbilical cord blood to form a single composite service which should be treated in a single way for VAT purposes.

109. I am aware that a recent reference for a preliminary ruling from the VAT and Duties Tribunal, Manchester, (57) raises questions as to whether the various constituent elements of the overall service of the collection, transportation, analysis, storage and making available of umbilical cord blood and the stem cells it contains should be regarded as separate services for VAT purposes, with possibly differing results as regards exemption.

110. Since that case was at an early stage in the procedure when the date of the hearing in the present case was fixed, the two cases have not been joined or dealt with together.

111. Consequently, the Court has not received in the present case any observations which might

have a bearing on the question of separate treatment. Nor has the Østre Landsret sought any guidance on that question. I have accordingly refrained from addressing it in any way in the present Opinion, although I am aware that the answer might have an impact on the way CopyGene's services are treated for VAT purposes.

Conclusion

112. In the light of all the above considerations, I propose that the Court should give the following answers to the questions raised by the Østre Landsret:

(1) A service such as the collection, transportation, analysis and storage of umbilical cord blood is to be regarded as closely related to hospital or 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 if the blood collected can be used for the purpose of such care, is collected for that purpose and cannot be used for any other purpose. It is irrelevant in that regard whether such care is specifically envisaged at the time the service is provided.

(2) A service which does not seek to avert, avoid or prevent the occurrence of a health disorder, or to detect such a disorder in a latent or incipient state, is not a preventive medical service covered by Article 13A(1)(b) of the Sixth Directive.

(3) In order to qualify for the exemption provided for in Article 13A(1)(b) of the Sixth Directive, a body not governed by public law must

– provide its services under social conditions comparable to those applicable to bodies governed by public law;

– be of a similar nature to a hospital or centre for medical treatment or diagnosis; and

– be duly recognised for that purpose.

A decision of the national authorities not to grant such recognition is not precluded by

– the fact that services, such as the collection, transportation, analysis and storage of umbilical cord blood, are performed by professional health personnel or

– the fact that the establishment in question has obtained authorisation to handle stem cells from such blood pursuant to national legislation which implements 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,

but is supported by the fact that the establishment's activities are not covered by the public heath insurance scheme.

(4) The answers to questions 1 to 3 are not affected by whether the services are supplied with a view to autologous or allogeneic use.

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. Cross-references below to Directive 2006/112 thus do not imply identity of wording with the Sixth Directive.

3 – Provisions now in Articles 131 and 132(1)(b) to (d) of Directive 2006/112.

4 – Article 134(a) of Directive 2006/112. It may also be noted, although the point has not been raised and does not appear to be relevant in the present case, that transactions carried out by hospitals, but not covered by Article 13A(1)(b), may continue to be exempted by Member States which exempted them before 1 January 1978 (Article 28(3)(b) and (4) of the Sixth Directive, in conjunction with Annex F, point 10; Article 371 of Directive 2006/112, in conjunction with Annex X, part B, point 7).

5 – 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).

6 – Article 3(p) and (q) of the Tissues and Cells Directive defines allogeneic use as cells or tissues transplanted from one person to another and autologous use as cells or tissues removed from and transplanted back to the same person.

7 – Available at http://ec.europa.eu/european_group_ethics/docs/avis19_en.pdf.

8 – According to one source (Samuel et al., Umbilical cord blood banking: public good or private benefit?, *Medical Journal of Australia*, Vol. 188 No 9, May 2008, p. 533), the likelihood of autologous use in later life has been calculated as between 1 in 20 000 to 1 in 200 000 for any individual. Another source (Nietfeld et al., Lifetime probabilities of hematopoietic stem cell transplantation in the U.S., *Biology of Blood and Marrow Transplantation*, Vol. 14 No 3, March 2008, p. 316) puts the likelihood much higher (but stem cells from bone marrow and peripheral blood may also be used in autologous treatment, so that the likelihood may be lower where only cord stem cells are concerned).

9 – For a fuller picture I refer in particular – in addition to the EGE opinion cited at point 14 and footnote 7 above and the articles cited in footnote 8 – to Council of Europe Recommendation Rec(2004)8 of the Committee of Ministers to Member States on autologous cord blood banks, adopted on 19 May 2004; Jennifer Gunning, ‘Umbilical cord cell banking: a surprisingly controversial issue’, *Ethics*, *Law and Society*, Vol. 2, 2006, p. 17; M.B. Agarwal, ‘Umbilical cord blood transplantation: newer trends’, *Journal of the Association of Physicians of India*, Vol. 54, February 2006, p. 143; World Marrow Donor Association, Statement on the utility of autologous or family cord blood unit storage, adopted on 25 May 2006; Royal College of Obstetricians and Gynaecologists, *Umbilical cord blood banking*, Opinion paper 2 of the Scientific advisory committee, revised in June 2006; David Batty, ‘Umbilical cord best treatment for childhood leukaemia’, *Guardian*, 8 June 2007; Haller et al., ‘Autologous umbilical cord blood infusion for type 1 diabetes’, *Experimental Hematology*, Vol. 36 No 6, June 2008, p. 710; and the website http://parentsguidecordblood.org/.

10 – The date is given in the EGE opinion cited at point 14 and footnote 7 above. Although bone marrow stem cell transplants commenced earlier, it appears that they, too, did not ‘take off’ until the 1980s (see Frederick R. Appelbaum, ‘Hematopoietic-Cell Transplantation at 50’, *New England Journal of Medicine*, Vol. 357, 11 October 2007, p. 1472).

11 – And, indeed, still in Article 131 et seq. of Directive 2006/112.

12 – See, most recently, Case C?253/07 *Canterbury Hockey Club and Canterbury Ladies Hockey Club* [2008] ECR I?0000, paragraphs 16 to 18, and the case-law cited there. In a similar vein, Advocate General Jacobs, contrasting the notions of 'strict' and 'restrictive' interpretation, said that 'exemptions from VAT should be strictly interpreted but should not be whittled away by interpretation. … As a corollary, limitations on exemptions should not be interpreted narrowly, but nor should they be construed so as to go beyond their terms. Both the exemptions and any limitations on them must be interpreted in such a way that the exemption applies to that to which it was intended to apply and no more' (Opinion in Case C?267/00 *Zoological Society of London* [2002] ECR I?3353, point 19).

13 – See, for example, Joined Cases C?394/04 and C?395/04 *Ygeia* [2005] ECR I?10373, paragraph 19 and the case-law cited there; and Case C?425/06 *Part Service* [2008] ECR I?897, paragraph 52 and the case-law cited there.

14 – See *Ygeia*, paragraphs 27 and 28 and the case-law cited there.

15 – See Case C?106/05 *L.u.P.* [2006] ECR I?5123, paragraphs 25 to 27 and the case-law cited there; see also *Ygeia*, paragraph 24.

16 – See Case C?212/01 *Unterpertinger* [2003] ECR I?13859, paragraph 42.

17 – See *Ygeia*, paragraphs 18 and 25 and the case-law cited there.

18 – See *Unterpertinger*, paragraph 40.

19 – Case C?141/00 *Kügler* [2002] ECR I?6833.

20 – Case C?45/01 *Dornier* [2003] ECR I?12911.

21 – Case 307/01 *D'Ambrumenil and Dispute Resolution Services* [2003] ECR I?13989.

22 – *L.u.P.*

23 – Case C?384/98 *D.* [2000] ECR I?6795.

24 – *Kügler*.

25 – *Unterpertinger*; *D'Ambrumenil and Dispute Resolution Services*.

26 – Case C?76/99 *Commission* v *France* [2001] ECR I?249, paragraph 24 et seq.

27 – *Ygeia*.

28 – That limitation appears to be contained in CopyGene's contract with the parents. Counsel for both CopyGene and the Danish Government stated at the hearing that it was also imposed by Danish legislation. It cannot of course be ruled out that, in other circumstances, umbilical cord blood may be collected for purposes of scientific research or other purposes which do not constitute hospital or medical care. When the purpose is unrelated to such care, the exemption in issue here cannot, of course, apply.

29 – See point 26 above.

30 – See also my Opinion in Joined Cases C?402/07 and C?432/07 *Sturgeon* and *Bock and Lepuschitz* [2009] ECR I?0000, points 93 and 94.

31 – *Dornier*, paragraph 35; *Ygeia*, paragraph 18.

32 – See, for example, Case C?110/94 *INZO* [1996] ECR I?857 and Case C?37/95 *Ghent Coal Terminal* [1998] ECR I?1.

33 – See Case C?287/00 *Commission* v *Germany* [2002] ECR I?5811, paragraphs 48 and 49; *Ygeia*, paragraphs 26 and 27.

34 – See, for example, *Unterpertinger*, *D'Ambrumenil and Dispute Resolution Services* and *L.u.P.*

35 – See, however, point 43 above.

36 – See point 57 above.

37 – See paragraph 52 of the judgment.

38 – Paragraphs 64 to 67.

39 – Which exempts 'the supply of services and of goods closely linked to welfare and social security work, including those supplied by old people's homes, by bodies governed by public law or by other organisations recognised as charitable by the Member State concerned'.

40 – *Dornier*, paragraphs 69 and 72 to 76; *Kügler*, paragraphs 56 to 58.

41 – See also my table in point 27 above.

42 – For the sake of completeness, I would recall that Article 13A(2)(a) of the Sixth Directive allows certain conditions to be imposed on bodies not governed by public law (see point 5 above). At the hearing, the Danish Government stated that Denmark had not made use of that provision. However, in other Member States, laboratories providing services comparable to those of CopyGene might be excluded from the scope of the exemption by one or more such conditions. It may also be borne in mind that Member States may lay down conditions for the purpose of ensuring the correct and straightforward application of all the exemptions in Article 13A(1) and of preventing any possible evasion, avoidance or abuse.

43 – OJ 1973 C 80, p. 1, Article 14A(1)(b).

44 – See B.J.M. Terra and J. Kajus, *A Guide to the Sixth VAT Directive*, IBFD, 1991, Vol. A, p. 587.

45 – COM(83) 426 final, pp. 44 and 45.

46 – COM(84) 648 final (OJ 1984 C 347, p. 5).

47 – See also point 26 above.

48 – See, by way of analogy, *Dornier*, paragraph 75.

49 – Also widely expressed in the literature (see, inter alia, the references in footnotes 8 and 9 above).

50 – At paragraph 72.

51 – See, however, point 43 above.

52 – See point 37 and footnotes 23 and 25 above.

53 – See points 74 and 86 above.

54 – See also point 48 above.

55 – Defined in Article 3(l) as use ‘on or in a human recipient and extracorporal applications’.

56 – See point 87.

57 – Case C-86/09 *Future Health Technologies.*