KBH

EXEMPTION - whether genetically engineered Factor VIII is a product derived from human blood or is human tissue - appeal dismissed - VATA 1994 s 31 and Sch 9 Grp 7 Items 7 and 8 - EEC Sixth Council Directive (77/388/EEC) Article 13A 1(d)

ENTERED 20/1

103-2224-39

LONDON TRIBUNAL CENTRE

BAXTER HEALTHCARE LIMITED Appellant

- and -

THE COMMISSIONERS OF CUSTOMS AND EXCISE Respondents

Tribunal: DR A N BRICE (Chairman)
MR J N MENDELSOHN
PROFESSOR R SPECTOR MD PhD FRCP FRCPath

Sitting in public in London on 14 and 15 November 1996

Mr Andrew Hitchmough of Counsel, instructed by McKenna & Co Solicitors, for the Appellant

Mr Kenneth Parker QC, instructed by the Solicitor for the Customs and Excise, for the Respondents

DECISION

1. Baxter Healthcare Limited (the Appellant) appeals against a decision of Customs and Excise dated 7 December 1995 that supplies by the Appellant to the National Health Service of recombinant Factor VIII, known as Recombinate, are taxable at the standard rate and are not exempt supplies. The decision was expressed to take effect from 1 November 1995.

2. Section 31 of the Value Added Tax Act 1994 (the 1994 Act) provides that a supply is exempt if it is of a description specified in Schedule 9. Group 7 of Schedule 9 is headed "Health and Welfare" and includes the following Items:

> "6 Human blood
>
> 7 Products for therapeutic purposes derived from human blood
>
> 8 Human (including foetal) organs or tissue for diagnostic or therapeutic purposes or medical research."

3. These provisions were first introduced by the Value Added Tax (Health) Order 1983 to implement the provisions of Article 13A 1(d) of the EEC Sixth Council Directive (77/388/EEC). Article 13A provides:

> "1. 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:
>
> (d) supplies of human organs, blood and milk."

4. The parties agreed that recombinant Factor VIII was not human blood and so did not fall within Item 6 of Group 7. It was also agreed that recombinant Factor VIII was for therapeutic purposes. Accordingly, the issues for determination in the appeal were:

> (1) whether recombinant Factor VIII was "a product ... derived from human blood" within the meaning of Item 7 of Group 7; or
>
> (2) whether recombinant Factor VIII was "human ... tissue" within the meaning of Item 8 of Group 7.

5. At the hearing an agreed bundle of documents was produced by the parties. Not all the documents were referred to at the hearing. Oral evidence was given on behalf of the Appellant by Professor Edward George Denley Tuddenham, Professor of Haemostasis for the Haemostasis Research Group at the Royal Postgraduate Medical School at Hammersmith Hospital. Professor Tuddenham illustrated his evidence on a flip chart which was then put in evidence. Oral evidence was given on behalf of Customs and Excise by Dr Trevor William Barrowcliffe, Head of the Haematology Division at the National Institute for Biological Standards and Control. The Appellant exhibited two small bottles, one of which contained a white powder being plasma derived Factor VIII and the other contained what appeared to be an identical white powder being recombinant Factor VIII. After the hearing we asked the parties to supply some further information and an agreed statement was sent to us on 20 December 1996 in response to that request.

6. From the evidence before us we find the following facts which were not in dispute.

7. Factor VIII is a complex protein found in human blood plasma which is essential to blood clotting. A deficiency of Factor VIII results in haemophilia. The gene for Factor VIII is carried on the X chromosome. Females have two X chromosomes but males have only one. Thus a defective X chromosome can be masked in females but not in males. This explains why almost all haemophiliacs are male. There are about 6,000 haemophiliacs in the United Kingdom. The severity of haemophilia varies according to the individual's factor activity level. Those with severe haemophilia are likely to experience spontaneous bleeding with no apparent cause. Those with moderate or mild haemophilia are more likely to experience bleeding as a result of trauma or injury. Bleeding can be minor, such as from nose bleeds and bruising, or major, such as bleeding in the joints, muscles and the central nervous system. All bleeds require immediate treatment. If muscle or joint bleeding is left too long it can cause irreparable damage and lead to crippling and reduced life expectancy.

8. Haemophiliacs require life long treatment and medical care for haemophiliacs is provided by haemotologists at specialist hospital centres. The current treatment is to replace or add the missing Factor VIII. Factor VIII is produced as a freeze dried concentrate with the appearance of white powder. Each individual dose is supplied in a small bottle. The patient adds distilled water to the bottle and then injects the solution intravenously either at the time of bleeding or regularly, usually three times a week. Regular treatment is the preferred option and is usually prescribed for children up to the age of eighteen. In the past, the main limitations on regular treatment have been the availability of supplies and the cost. The total current annual usage of Factor VIII in the United Kingdom is 160 million international units at a cost of around £40M.

9. There are two main types of replacement Factor VIII currently available. The first is derived from plasma taken from human blood donations. Many thousands of donors are needed to make a batch of Factor VIII. Such Factor VIII can be either "high purity" or "intermediate purity". High purity Factor VIII is purified using monoclonal antibodies and costs about 32 pence per standard unit. Intermediate purity Factor VIII contains extraneous protein molecules. Sometimes it has been purified using conventional chromatography. It used to be the treatment of choice and is still sometimes used. It costs 18 pence per standard unit. Before 1984 haemophiliacs were unknowingly at risk from viral infection, including HIV and hepatitis, by receiving contaminated plasma derived Factor VIII. In 1984 screening and virus inactivation procedures were introduced to minimise this risk but there are still potential concerns about the virus safety of plasma blood products. Customs and Excise agree that plasma derived Factor VIII is exempt from value added tax.

10. The second main type of replacement Factor VIII is genetically engineered recombinant Factor VIII such as is supplied by the Appellant. As mentioned, Factor VIII is a protein found in human blood plasma. The atoms which make up a human cell are mainly those of the elements hydrogen, carbon, oxygen and nitrogen. But these elements combine into molecules many of which make up a cell. Among these are protein molecules which are manufactured in the parts of cells outside the nucleus called the cytoplasm. Proteins break down into twenty different smaller molecules called amino acids which are the building blocks of proteins. They join together in long chains called polypeptides to form many thousand different types of protein. Some proteins contain a few dozen amino acids and some have thousands. Each protein is a unique sequence of amino acids which gives it a distinct three-dimensional structure upon which its properties depend. Factor VIII is a protein with a sequence of 2,332 amino acids.

11. In humans genetic information is carried by genes and each individual may have about 100,000 genes. The genes consist of DNA (deoxyribonucleic acid) which is a molecule in the form of a double helix which exists in the nucleus of the cell. The complete genetic information content of human DNA is about 3,000 million base pairs long and human Factor VIII consists of some 190,000 base pairs. Most genes consist of short segments that contain the coding information for proteins with longer intervening segments called introns. DNA does not itself cause the production of proteins but a particular section of DNA will contain the genetic information for the production of a particular protein. The manufacture of a protein begins when a segment of DNA unwinds in order that one of the strands containing the information about the amino acid sequence of a particular protein can be copied from the DNA into RNA (ribonucleic acid). It then becomes spliced so that the introns are removed and the continuous coding sequence for protein, called messenger RNA, is produced. The messenger RNA then forms a template from which adaptor molecules can deliver the appropriate amino acid. The amino acids can then combine to form a polypeptide chain of a particular protein.

12. DNA is contained in each cell in the body but the body divides its functions between different cells and it is the liver cells which make the proteins which go into the blood, including Factor VIII. When the sequence of the 2,332 amino acids which form human Factor VIII has been produced in the liver cells of the normal individual it is secreted out of those cells and from there it enters the blood stream. As the gene for making Factor VIII is absent or defective in haemophiliacs their liver cells do not make Factor VIII, or make it in inadequate quantities, and that is why replacement Factor VIII is required.

13. The Appellant's manufacturing process has been under development since 1984 and we have found it convenient to consider the process in three steps. The first step was to find the Factor VIII gene. In 1984 a number of papers were published in scientific journals which described how pure Factor VIII derived from human blood had been analysed and its chemical structure, namely the sequence of 2,332 amino acids of which Factor VIII consists, had been established. The Appellant had already purified porcine Factor VIII, which behaves exactly like human Factor VIII as far as coagulation is concerned, from pig's blood. From the purified porcine Factor VIII the Appellant deduced the relevant porcine DNA and this was used to screen a human genomic DNA library which led to the isolation of part of the human Factor VIII gene.

14. The second step was to produce the relevant copy DNA. The human Factor VIII gene fragments were used to screen human liver tissue to identify the messenger RNA which was then extracted from the human liver cells. The messenger RNA was then exposed to a reverse transcriptase enzyme which then formed copy DNA (cDNA). The cDNA was then assembled in an expression vector.

15. The third step was to manufacture the Factor VIII commercially. The cDNA produced under the second step was introduced into the nucleus of the ovary cells of Chinese hamsters where it became integrated into the DNA of the hamster cells. The cells with the incorporated cDNA were allowed to proliferate to form a cell line which has since been stored in a master cell bank at -135 degrees Centigrade. All Recombinate that has been produced and will be produced in the future derives from this cell bank. The cells exist in a culture medium which contains the appropriate chemicals to enable proteins to be produced. The modified DNA in this cell line directs the formation of messenger RNA which, in turn, directs the synthesis of Factor VIII which is released into the culture medium. The Factor VIII is then purified and stabilised. The final product is freeze dried and appears as a white powder. Recombinate was first put through clinical trials in 1987.

16. The only component of human origin in the whole process is the messenger RNA which was extracted from human liver cells in the second step and it will be recalled that messenger RNA lacks the introns which are present in DNA. The

Appellant's manufacturing process ensures that there should be no human DNA or RNA in the final product although such may appear in "vanishingly small" amounts. On the other hand the molecular structure of recombinant Factor VIII is the same as human Factor VIII and has precisely the same amino acid sequence.

17. Recombinant Factor VIII has been available as a commercially produced product in the United Kingdom since May 1995. It is now considered as the treatment of choice by most clinicians and by the Haemophilia Society. It costs approximately 50-54 pence per standard unit including value added tax. It has the advantages of: an unlimited supply; a renewable source; and freedom from blood borne viral contamination. We accept the evidence of both witnesses that plasma derived Factor VIII and recombinant Factor VIII are practically chemically indistinguishable although in some tests recombinant Factor VIII might behave differently from plasma derived Factor VIII. For example, monoclonally purified plasma derived Factor VIII, despite viral inactivation procedures, might contain low levels of viral contamination.

18. Before September 1995 Customs and Excise accepted that recombinant Factor VIII was exempt from value added tax in the same way as plasma derived Factor VIII. However, Customs and Excise then decided that recombinant Factor VIII was not derived from human blood nor was it human tissue and so was not exempted by Items 7 or 8 of Group 7 of Schedule 9 of the 1994 Act. It is against that decision that the Appellant appeals.

19. On behalf of the Appellant Mr Hitchmough submitted that both plasma derived Factor VIII and recombinant Factor VIII were products for therapeutic purposes derived from human blood and should be exempt under Item 7 of Group 7 of Schedule 9 of the 1994 Act. His main submission was that the provisions of the 1994 Act should be given an updated construction to take into account developments in medical science since the date of its enactment. He cited *Bennion* section 288 at page 617 as authority for the view that Parliament intended courts to apply to an ongoing Act a construction that gave effect to its original intention by continuously updating its wording to allow for changes that had occurred since the passing of the Act. This approach had been followed in *Gambart v Ball* (1863) 32 LJCP 166; *Barker v Wilson* [1980] 1 WLR 884; and *Derby & Co Ltd v Weldon (No 9)* [1991] 1 WLR 652. It was, therefore, necessary to identify the legislative intention and then to apply the updated principle of construction, taking into account those developments in technology consistent with the legislative intention.

20. Mr Hitchmough went on to submit that it was the legislative intention of the Sixth Directive to exempt from tax the supplies of those elements and substances of human origin which could usefully be used in medical research or for treating other human beings. Recombinant Factor VIII was derived from human genetic material and so its source material was human. He referred to *Terra and Kajus: A Guide to*

European VAT Directives Volume II at page 59. He also referred to the Spanish language text of the Directive in which Article 13A 1(d) appeared as: "Las entregas de organos, sangre, leche y otros elementos del cuerpo humano". The reference to "other elements of the human body" supported the view that the general intention was to exempt those parts of the human body which could be used to treat other human beings and this intention had to take into acount that medical science had progressed significantly since the publication of the Directive. Also, in considering the legislative intention of the 1994 Act it was necessary to bear in mind that the 1994 Act was a consolidating Act and that the provisions now in Items 6, 7 and 8 of Group 7 were originally enacted in 1983 and had remained unchanged since then. The 1983 provisions were enacted to implement the 1977 Directive and had added the words "tissue" and "products derived from human blood" to the words in the Directive. This indicated that in 1983 the United Kingdom was updating the construction of the Directive to take into account developments since 1977 and further significant developments had taken place since 1983.

21. Mr Hitchmough's alternative submission on the first issue in the appeal was that, analysed in terms of its structure and information content, recombinant Factor VIII was "derived from human blood" within the meaning of Item 7. The words "derived from" were wider than the words "derived out of" and did not mean "extracted from". He referred to the Oxford English Dictionary which gave a number of meanings for the word "derive". These included: "to convey from one to another, as by transmission, descent, etc" and "to hand on". In the Appellant's process the biochemical fingerprint in human blood had been identified and handed on through the genetic engineering process. Other definitions were: "chemical: to obtain a compound from another by partial replacement" and "to obtain by reasoning". The origin of recombinant Factor VIII could be traced back to human blood as it had been necessary to isolate and identify the DNA responsible for Factor VIII production in human blood before copying it using the animal cell based procedure. The biochemical structure of human Factor VIII had been used as a biochemical fingerprint for the genetic engineering process. That was a very close logical connection with human blood.

22. On the second issue in the appeal Mr Hitchmough submitted that recombinant Factor VIII should be exempt under Item 8 of Group 7 but did not develop this submission in detail.

23. Finally, Mr Hitchmough submitted that for social reasons recombinant Factor VIII should be exempt. Plasma derived Factor VIII and recombinant Factor VIII were biochemically indistinguishable and were used for an identical purpose. The only difference between the two products was that recombinant Factor VIII was safer as it was free from blood borne viral contaminations. Both products should attract the same treatment for value added tax purposes and both should be exempt. If plasma derived Factor VIII were to be exempt from value added tax and

recombinant Factor VIII were to be standard-rated, clinicians could not afford to prescribe recombinant Factor VIII. Such an adverse social consequence could not have been the intention of Parliament.

24. On behalf of Customs and Excise Mr Parker submitted that Recombinant Factor VIII was not a product derived from human blood within the meaning of Item 7 of Group 7. The views in *Bennion* should be approached with caution as they did not refer to Community law. In his view, one had first to determine what was covered by the exemption in the Sixth Directive and then interpret the national legislation accordingly. Article 13A 1(d) only exempted supplies of human organs, blood and milk. In construing these provisions the principle was that exemptions should be strictly construed and he cited *EC Commission v The Netherlands* [1987] ECR 1471 at page 1480 and page 1489. He submitted that the underlying purpose or rationale was to exempt products which depended on provision by human donors so that a continuing supply would be encouraged. Also, national legislation had to be construed as far as possible to conform with Community law; he cited *Webb v EMO Air Cargo (UK) Ltd* [1993] 1 WLR 3 and *Marleasing S.A. v a Comercial Internacional de Alimentacion S.A.* [1990] ECR 1-4135. He accepted that the wording of Items 6, 7 and 8 in Group 7 appeared to go beyond the provisions of Article 13A 1(d) by referring to "products derived from human blood" but this could be explained if the view was taken that the word "blood" was wide enough to cover products derived from it which depended upon continuing provision by human donors. Thus the words in the national legislation were within the intention of the Directive. He relied upon the Explanatory Note to the 1983 Order which stated:

> "This Order exempts from value added tax supplies of human blood, blood products for therapeutic purposes and of human organs and tissue for diagnostic or therapeutic purposes or medical research."

25. Dealing with Mr Hitchmough's alternative argument on the first isue in the appeal, Mr Parker did not agree with the definitions of "derived" adopted by Mr Hitchmough. In his view the words "derived from" meant "made from" or "extracted from" or "prepared from". The starting point for the Appellant's production process was the Chinese hamster ovary cells which contained the Factor VIII gene but in a different form from that which existed in human tissues. The production of the bulk Factor VIII for Recombinate did not require the use of human tissues or human blood. Genetically engineered products, which were not dependent upon the continuing provision of blood by human donors, were not derived from human blood and so were not within the exemption even though human blood had been used to obtain information at some time in the history of the scientific development of the product.

26. Turning to the second issue in the appeal Mr Parker argued that, although human liver tissue had been used in the development process, recombinant Factor

VIII was not extracted from that tissue; it was messenger RNA which was taken from the liver tissue and used to make cDNA by the process of reverse transcription which did not normally take place in human blood and tissues. It followed that the subsequent production of Factor VIII was an essentially artificial process not an extraction from tissue in its natural form.

27. In considering the submissions of the parties we begin with the first issue for determination in the appeal which is whether recombinant Factor VIII is "a product for therapeutic purposes derived from human blood" within the meaning of Item 7 of Group 7 of Schedule 9 of the 1994 Act. Mr Hitchmough relied upon *Bennion* and urged us to give an updated construction to this phrase to take account of developments in medical science since the date the provision was first enacted in 1983. Mr Parker urged caution because different provisions applied to the interpretation of statutes which implemented European Directives.

28. Section 288(2) of *Bennion* sets out the following principle:

> "It is presumed that Parliament intends the court to apply to an ongoing Act a construction that continuously updates its wording to allow for changes since the Act was initially framed (an updating construction). ... This means that in its application on any date, the language of the Act, though necessarily embedded in its own time, is nevertheless to be construed in accordance with the need to treat it as current law."

29. The subsequent commentary includes the following:

> "In construing an ongoing Act, the interpreter is to presume that Parliament intended the Act to be applied at any future time in such a way as to give effect to the true original intention. Accordingly the interpreter is to make allowances for any relevant changes that have occurred, since the Act's passing, in law, social conditions, technology, the meaning of words, and other matters. ... An enactment of former days is thus to be read today, in the light of dynamic processing received over the years, with such modification of the current meaning of its language as will now give effect to the original legislative intention."

30. In discussing the allowances to be made for changes that occur as a result of developments in technology *Bennion* states:

> "The nature of an ongoing Act requires the court to take account of changes in technology, and treat the statutory language as modified accordingly when this is needed to implement the legislative intention. ... If however changed technology produces something which is altogether beyond the scope of the original enactment, the court will not treat it as covered."

31. As an example of the former *Bennion* suggests that the reference to "the military or naval service" in the Foreign Enlistment Act 1870 should be taken as including an air force service. As an example of the latter *Bennion* cites *Kingston Wharves Ltd v Reynolds Jamaica Mines Ltd* [1959] AC 187 where the Judical Committee of the Privy Council held that it was not the intention of the legislature that 18,000 lb powered tractors should come within the meaning of "carriages" in an 1895 law. The three authorities cited by Mr Hitchmough were cited by *Bennion* as examples of allowances by the courts for developments in technology. *In Gambart v Ball* (1863) the issue was whether the publication and sale of photographic copies of an engraving in which there was a subsisting copyright was an infringement of statutes passed for the protection of artists and engravers. It was held that it was. The statute provided that if any person should "engrave, etch or in any manner copy" engravings without consent he should be liable to an action. The court held that a photgrapher who had taken a photograph of an engraving had "in any manner copied" it; the object of the statute was to secure to the artist the commercial value of his property. The very wide and general words of the statute should be construed according to their plain and ordinary meaning and be held to apply to any mode of copying known at that time "and to such other modes of multiplying copies as the ingenuity of man may from time to time discover". In *Barker v Wilson* (1980) the court held that the definition of "bankers' books" in section 9 of the Bankers' Books Evidence Act 1879 was wide enough to include any form of permanent record kept by the bank of transactions relating to the bank's business, made by any of the methods which modern technology made available including, in particular, microfilm. In *Derby v Weldon* (1991) the court held that the database of a computer, insofar as it contained information capable of being retrieved and converted into readable form, was a "document" of which the court could order discovery.

32. Both *Bennion* and the three authorities cited by Mr Hitchmough emphasise that the purpose of any updated construction is to give effect to the presumed intention of Parliament and to give effect to the original legislative intention. Accordingly, we have considered the words in Item 7 in the context in which they appear to see if we can identify the legislative intention. The context makes it clear that the words of Item 7 were enacted to implement Article 13A 1(d) of the Sixth Directive and we note that the provisions of Article 13A 1(d) are much narrower than those of Item 7 of Group 7 and refer only to human organs, blood and milk. It is a principle of European law that provisions should be interpreted having regard to their purpose and we have tried to identify the purpose or rationale behind the exemption in Article 13A 1(d). Mr Hitchmough suggested that this was "to exempt from tax the supplies of those elements of human origin which could usefully be used in medical research or for treating other human beings". He relied upon *Terra and Kajus* but that publication only indicates that the proposal for the Sixth Directive restricted the exemption to human blood and milk and that the text which was adopted extended the exemption without commentary to supplies of human organs. Mr Hitchmough also relied upon the Spanish version of Article 13A 1(d) and its

reference to "other elements of the human body". This, of course, appears in the same context as "organs, blood and milk". The parts of the human body which are not organs, blood and milk could, perhaps, best be described as tissue and, in our view, that is the most likely meaning of "other elements of the human body". Mr Parker suggested that the purpose or rationale of Article 13A 1(d) was "to exempt products which depended upon provision by human donors so that a continuing supply would be encouraged". He had no authority for this view.

33. In the absence of any compelling evidence about the purpose or rationale of Article 13A 1(d) we have not been able to accept either of the suggestions put to us. It is a principle of European law, accepted by Mr Hitchmough, that exemptions must be strictly construed. We note that the words of Article 13A 1(d) refer to naturally occurring parts of the human body only and not to products produced as a matter of manufacture and production and, in the light of the information available to us we are unable to discern that it is the intention of the Directive that the exemption in Article 13A 1(d) should be extended so that it should apply not only to naturally occurring parts of the human body but also to products such as recombinant Factor VIII produced as a matter of manufacture or production.

34. As Item 7 of Group 7 was enacted to implement Article 13A 1(d) our conclusion on the Directive would point towards the conclusion that recombinant Factor VIII was not exempt under Item 7 of Group 7. However, the national legislation is somewhat wider than the Directive and, where national legislation is more favourable to the Appellant than the Directive, then the Appellant can rely upon the national legislation subject, however, to the principle that where there is an ambiguity in the national legislation the latter should be construed as far as possible to comply with the purpose and wording of the Directive.

35. We have, therefore, tried to identify the legislative intention of the 1994 Act and have concluded that the legislative intention of the 1994 Act is similar to that of the Directive, namely that naturally occurring parts of the human body, which are not produced as a matter of manufacture or production, are exempt but that those parts need not necessarily be in the same form as they appear in the body but may be extracted from it; for example, if red blood cells were extracted from a donor's blood and used to treat a patient, that would not be blood but would be derived from blood and it is the legislative intention that such derivative products should be exempt. We note that the Act which we have to interpret is the Value Added Tax Act 1994. We accept that that Act contains provisions originally contained in the 1983 Order, and we also accept that there have been substantial changes in the technology used in genetic engineering since 1983. However, the fact remains that the Act we have to interpret is only two years old.

36. Having considered Mr Hitchmough's main submission on the first issue in the appeal we agree with the principle that an updating construction should be used

to give effect to the intention of the legislature but conclude that the intention of the legislature when enacting the 1983 Order and the 1994 Act was only to exempt naturally occurring parts of the human body and not to exempt substances produced as a matter of manufacture or production. In our view this is a case where changed technology has produced something which is altogether beyond the scope of the original enactment. Accordingly, we conclude that it was not the legislative intention that recombinant Factor VIII should be exempt.

37. Mr Hitchmough's alternative argument on the first issue in the appeal was that the word "derived" did not mean "extracted from" but meant "conveyed by transmission or descent"; a physical connection was not necessary and, because recombinant Factor VIII was made using information originally obtained from human blood, it was "derived" from human blood. We have therefore considered the meaning to be given to the word "derived". If the word means that there must be some physical connection between the thing derived and the thing from which it is derived then the Appellant cannot succeed because there is no physical connection between human blood and recombinant Factor VIII. We accept that the information about the molecular structure of Factor VIII and its 2,332 amino acids was originally obtained by analysing human blood but no human blood was used in the Appellant's manufacturing and development process. In the second step of the Appellant's process human liver tissue was used to indentify and extract the messenger RNA but liver cells are not part of human blood.

38. To assist us in identifying the appropriate meaning of the word "derived" we have once again considered the legislative intention of both the Directive and the 1994 Act and also the context in which the phrase "derived from" occurs. In our view Item 7 of Group 7 exempts naturally occurring parts of the human body only and so it follows that there must be some physical connection between the thing derived and the thing from which it is derived, so that the ultimate product can be seen as something which is a part of a naturally occurring part of the human body and not something which is manufactured or produced without any physical connection with a part of a human body. Bearing in mind that the words "derived from human blood" in Item 7 of Group 7 are an extended version of the words which appear in the Directive, and bearing in mind that exemptions must be strictly construed, and also that we must interpret our national legislation as far as possible to comply with the wording and purpose of the Directive, we do not consider that we would be justified in extending the meaning of the Directive still further so as to exempt a product which is not physically derived from human blood. It follows that, as Recombinant Factor VIII has no physical connection with human blood, it is, in our view, not "derived" from human blood.

39. On the first issue in the appeal we therefore conclude that recombinant Factor VIII is not exempt under Item 7 of Group 7 because it is not derived from human blood.

40. The second issue for determination in the appeal is whether recombinant Factor VIII is human tissue within the meaning of Item 8 of Group 7. Although Mr Hitchmough submitted that recombinant Factor VIII should be exempt under Item 8 of Group 7 he made no detailed submissions on this point. In our view the product is not exempt under Item 8 because it is not human tissue. Although there may possibly be an argument that it is derived from human tissue, inasmuch as messenger RNA from human liver cells was used at the second stage in the Appellant's process, that does not assist the Appellant because Item 8 does not exempt products derived from human tissue, but only human tissue. On the second issue in the appeal we therefore conclude that recombinant Factor VIII is not exempt under Item 8 of Group 7 as it is not human tissue.

41. We have considered very carefully the submissions made to us by Mr Hitchmough about the social desirability of exempting recombinant Factor VIII. He said that if plasma derived Factor VIII were to be exempt from value added tax and recombinant Factor VIII were to be standard-rated, clinicians could not afford to prescribe recombinant Factor VIII. However, there was no evidence before us that that would necessarily follow. The National Health Service must have to make very many decisions about the purchasing of products, some of which may cost more than others. Such decisions are for the National Health Service alone and are made with the health of patients in mind.

42. In any event, it is not for us to say, other than on legal grounds, what products should be exempt and what products should be standard-rated. That is the task of Parliament which has expressed its views in the 1994 Act which itself was enacted to comply with the United Kingdom's treaty obligations to implement the Sixth Directive. We must apply the law, as contained in the 1994 Act and the Sixth Directive, to the product produced by the Appellant. And in applying the law we must follow established legal principles. We must give effect to the intention of Parliament; we must interpret the 1994 Act on the basis that it is intended to implement the Sixth Directive; we must try to give effect to the purpose of the Sixth Directive; and exemptions in the Directive must be strictly construed. Bearing in mind that the words of the Directive refer to human blood and other naturally occurring parts of the human body only we interpret the words "product ... derived from human blood" in the 1994 Act to extend the words in the Sixth Directive only to products which are physically derived from human blood. We agree that this means that two identical substances, namely plasma derived Factor VIII and recombinant Factor VIII, have to be treated differently for value added tax purposes but it seems to us that that must follow from the words of the 1994 Act and of the Sixth Directive. The legislation does not exempt products by reference to their chemical composition but by reference to the matter from which they are derived.

43. Our decisions on the issues for determination in the appeal are:

(1) that recombinant Factor VIII is not a "product ... derived from human blood" within the meaning of Item 7 of Group 7; and

(2) that recombinant Factor VIII is not "human ... tissue" within the meaning of Item 8 of Group 7.

44. The appeal is, therefore, dismissed. There will be no order as to costs.

GRO-C

DR A N BRICE

CHAIRMAN

RELEASE DATE: 17/1/97

LON/96/177