Dr Ferdinando

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PATENTS ACT 1977

IN THE MATTER OF an application under Section 72 by Genencor International for the revocation of Patent No GB 2091271 in the name of Collaborative Research Inc.

23/6/9

INTERIM DECISION

The application for the patent in suit was made on 15 January 1982 claiming priority from two earlier applications filed in the United States of America and dated 16 January 1981 and 1 December 1981 respectively.

Application for revocation was made on 19 June 1990. In the statement accompanying the application the applicants contend that every claim of the patent is invalid under Section 72(1)(a) and (c), that is on the grounds of lack of novelty, lack of inventive step and insufficiency.

A counterstatement was filed by the patentees on 14 March 1991 together with two sets of amended claims. Set A was offered firmly and unconditionally and, in the event that this set were to be found unallowable or invalid, Set B was offered under the same conditions. Shortly before the hearing, on 7 March 1994, a further set of claims, Set C, was offered on the basis that it should be considered if both Sets A and B were found to be wanting. Subsequent to the filing of their counterstatement the patentees filed a supplementary counterstatement on 14 June 1991 and a further counterstatement on 24 September 1991, the latter being in response to an amended statement filed by the applicants on 9 August 1991 to take account of the Set A claims.

The applicant's evidence was filed on 16 March 1992. It comprises a statutory declaration in the name of Dr Michael Samuel Neuberger together with exhibits MN1 and MN2, the former being Dr Neuberger's curriculum vitae and list of publications with which he has been associated, and the latter comprising a lengthy set of papers relating to techniques used

in recombinant DNA technology at about the time of and prior to the date of the patent in suit.

There then followed a considerable amount of correspondence, initiated by the patentees, concerning Dr Neuberger's suitability as an expert witness in the proceedings. This matter, in so far as it affected the proceedings prior to the hearing, was concluded by a letter dated 15 January 1993 from the patentees in which they agreed not to pursue their request for a preliminary hearing and confirmed that they would not be filing any evidence of their own. I shall return to the matter of Dr Neuberger's suitability as a witness at a later point in this decision.

At the hearing before me on 18 and 19 April 1994 the patentees were represented by their counsel, Mr Richard Hacon, and the applicants for revocation by their counsel, Mr George Hamer. Dr Michael Neuberger attended on behalf of the applicants for the purpose of cross-examination.

The patent in suit relates to recombinant DNA encoding a polypeptide displaying milk clotting activity and precursors thereof. In the disclosure the polypeptide is rennin and the precursors specifically mentioned are prorennin and preprorennin. These products are also known as chymosin, prochymosin and preprochymosin respectively and the terms were used interchangeably throughout the hearing.

The patent specification explains that the enzymatic protein rennin has long been known for coagulating milk casein in cheese making. However, its production from natural sources is difficult and costly and so the invention has as its primary aim the volume production of rennin by recombinant DNA techniques.

Following argument at the outset concerning the claims under consideration, an argument I shall return to later, I ruled that the hearing should go forward on the basis of the Set A claims which read as follows:-

1. A living cell containing genetic material derived from recombinant DNA material and capable of expressing pre-prorennin.

2. Pre-prorennin, whenever derived from a living cell according to claim 1.

3. A method of obtaining expression of pre-prorennin in host cells, said method comprising isolating a DNA sequence which codes for pre-prorennin, attaching a transcriptional promoter and attaching ribosomal binding sites to that sequence at the 5' end and varying the distance between the beginning of the DNA which codes for pre-prorennin and the segment of DNA carrying the promoter and binding site, transforming the DNA into host cells, cloning the host cells and selecting those which have high levels of expression of pre-prorennin.

4. A method of obtaining expression of prorennin in host cells, said method comprising isolating a DNA sequence which codes for pre-prorennin and having a 5' end, removing a portion from the 5' end which portion codes for the prorennin precursor polypeptide, ligating on to the remainder a synthetic piece of DNA carrying a translational initiation codon at the 3' end of said piece, attaching a transcriptional promoter and attaching a ribosomal binding site to the sequence at the 5' end and varying the distance between the beginning of the DNA which codes for prorennin and the segment of DNA carrying the promoter and binding site, transforming the DNA into host cells, cloning the host cells and selecting those which have high levels of expression of prorennin.

5. A method of obtaining the expression of rennin....[the rest follows as for claim 4 except that "prorennin" is replaced by "rennin"].

6. A method of obtaining rennin by recombinant DNA means, wherein rennin genetic material is obtained from pre-prorennin genetic material, after which said rennin genetic material is transformed into host cells and cloned.

7. A method of obtaining prorennin....[the rest follows as for claim 6 except that "rennin" is replaced by "prorennin"].

8. A method of obtaining pre-prorennin by growing cells containing genetic material obtained from recombinant DNA material and capable of expressing pre-prorennin.

9. A pre-prorennin gene comprising a nucleotide sequence coding for the amino acid sequence of pre-prorennin and excluding any intervening nucleotide sequences present in genomic DNA encoding pre-prorennin.

10. A pre-prorennin gene in accordance with claim 9 and having operatively attached thereto a vector which replicates in a host cell.

11. Escherichia coli as deposited in The American Type Culture Collection Accession number 31929.

12. Recombinant DNA material found in Escherichia coli American Type Culture Collection Accession number 31929, which encodes pre-prorennin and prorennin.

13. Saccharomyces cerevisiae American Type Culture Collection Accession number 20623.

14. Recombinant DNA material comprising prorennin nucleotide sequence [there then follows a nucleotide sequence for prorennin].

15. Recombinant DNA material comprising pre-prorennin nucleotide sequence [there then follows a nucleotide sequence for pre-prorennin]

16. Recombinant DNA material comprising rennin nucleotide sequence [there then follows a nucleotide sequence for rennin]

17. The use of recombinant DNA material comprising a pre-prorennin, prorennin or rennin nucleotide sequence in changing the genotype of a host bacterial, yeast or fungal cell as a result of incorporating said DNA material into said cell as part of the expressible genome of said cell.

18. A process for the production of pre-prorennin,prorennin or rennin comprising growing host cells genotypically changed as a result of the use of claim 17 to obtain pre-prorennin, prorennin or rennin, respectively.

19. Rennin, prorennin or pre-prorennin whenever obtained by carrying out a process of claim 18 using a cell genotypically changed as a result of the use of claim 17 to incorporate a rennin, prorennin or pre-prorennin nucleotide sequence, respectively, into said cell as part of the expressible genome of said cell.

20. Recombinant DNA material coding for a polypeptide signal sequence and having the following nucleotide and polypeptide sequence or other nucleotide sequence coding the said polypeptide [there then follows the nucleotide and polypeptide sequences].

Apart from claims 17 to 19 all the claims of Set A are to be found in the patent as granted. The applicants for revocation have, amongst other things, objected to the inclusion of claims 17 to 19 at this stage and I shall address this matter at a later stage in my decision.

As I have already indicated, the main issues I have to decide are those of novelty, inventive step and sufficiency of description. At the hearing both counsel addressed me at length on all of these with perhaps the greater emphasis being put on the inventive step argument. I propose, however, to deal first with the question of novelty if only for the reason that, if it were to be shown that some claims are lacking in novelty, it would then not be necessary to consider whether those same claims are lacking in inventive step. In their statement of case the applicants allege that the claims, in so far as they relate to bovine rennin, prorennin and preprorennin, DNA encoding it, and recombinant expression thereof, lack novelty under Section 2(3) of the Act by virtue of the disclosure in two European Patent Specifications,

namely Unilever (EP 0077109) and Celltech (EP 0068691). At the hearing no great emphasis was put on Celltech and, for the purposes of this decision, it is my intention to concentrate on the Unilever document in respect of the novelty argument under section 2(3).

Unilever has a priority date of 14 October 1981 and according to Mr Hacon this date (and for that matter the priority dates of Celltech) is not in dispute for the purposes of these proceedings. Of course, this date is intermediate the two priority dates claimed for the present patent, namely 16 January 1981 and 1 December 1981, and therefore Unilever is only effective under Section 2(3) if, for some reason, the earlier priority date claimed for the patent in suit is not valid.

It was Mr Hacon's opinion that, if the first priority document supports the invention claimed, that the first priority date must be valid. That is indeed what the Act provides under Section 5 and in support of his argument in this particular case Mr Hacon drew my attention to the recent, as yet unpublished, decision of Aldous J in the case of Biogen Inc v Medeva plc.

Mr Hamer's approach was somewhat more direct in so far as he cited Decision T81/87 - 3.3.2 of the Technical Board of Appeal in the EPO. This decision, which was published in the Official Journal of the European Patent Office 6/1990, relates to the European application equivalent to the present application. It was Mr Hamer's contention that, by virtue of this decision, the patentees have been deprived of their first priority date and, consequently, that Unilever anticipates by virtue of Section 2(3).

In his address in reply Mr Hacon requested that I be wary of the EPO decision for what I understand to be three reasons, first that the decision was obsessed with the situation as it related to preprorennin; second, that the evidence and the arguments before the EPO may have been different; and third, that just because one tribunal had decided the matter, it was not necessarily the case that they were right.

Taking the last point first it is, of course, undeniable that tribunals are not always right. That is why there is recourse to the courts to test the decisions of tribunals. I would,

however, need very strong reasons to convince me that the EPO decision was so wrong that I should not take it into careful account and, to my mind, no such reasons were put to me during the course of the hearing. Moreover, I note that Section 5 of the 1977 Act is one of those sections which, according to Section 130(7), is framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of, inter alia, the European Patent Convention. It seems to me, therefore, perfectly proper that I should take on board fully the effects of the EPO decision in coming to my decision on the present case.

Proceeding on that basis brings me to Mr Hacon's first point that the EPO decision was obsessed with the situation as it applied to preprorennin. By this I take him to mean that whilst the patent in suit may not be entitled to its priority date so as to retain claims relating to preprorennin, this is not necessarily the case when it comes to the prorennin and rennin claims. Indeed, in his summing-up on this matter, he was emphatic that the first priority document, namely that dated 16 January 1981, supports the claims to rennin and prorennin and therefore the Section 2(3) argument cannot be applied thereto.

It would appear then that, before I can consider the extent to which the Unilever document is a relevant citation under Section 2(3), I must come to an opinion as to what the EPO decision means in its conclusion at paragraph 13 by "the first priority document does not disclose all the critical features of the claimed invention as required." In doing so I am well aware of the need to look not only at the decision itself but at the submissions made by both Counsel at the hearing.

My first impression of the decision is that it is not, contrary to Mr Hacon's argument, obsessed with the situation as it affects preprorennin. Having come to the paragraph 13 conclusion it moves on to consider the relevance of Unilever as a novelty citation and, in paragraph 14, makes the statement that "In view of the above conclusion Claims 1 and 2 may only rely on the second priority date....". Claims 1 and 2 were part of the main set submitted by the patentee in the present case for the purpose of the appeal before the EPO. They related to a transformable living cell containing genetic material which is inter alia "capable of expressing bovine preprorennin" or "prorennin" respectively. It is therefore

clear to me that, in the view of the Technical Board of Appeal, the patentees are not entitled to the first priority date for prorennin as well as preprorennin and, if there is any doubt about the decision, it is over the situation concerning rennin itself. However, at paragraph 10 of the decision the following is made clear:-

> "It has been admitted that on the date of the first priority document, the idea of preparing prorennin **or rennin** (my emphasis) by the recombinant DNA technique was not reduced to practice by the Appelant."

In my view, therefore, the effect of the Board of Appeal's decision is to deprive the patentees of their first priority date for the idea of preparing preprorennin, prorennin and rennin by the recombinant technique. However, in the light of Mr Hacon's argument concerning this decision, I consider it to be only right that I approach the matter from another direction.

I will do this by looking initially at the first priority document and considering what the patentees had done as of 16 January 1981. What they thought they had done was to have prepared a phage 293-207 carrying the entire pre-prorennin sequence. This much is clear from the first priority document at lines 16 and 17 on page 17. All that follows thereafter in the first priority document is, on their own admittance at lines 18 and 19 on the same page, a theoretical indication of the procedure to be followed to achieve expression of preprorennin, prorennin or rennin using this sequence as a starting point.

It is only at the date of the second priority document that it becomes clear that none of the clones obtained carried the full preprorennin gene. Since phage 293-207 carried an insert bearing the sequence from nucleotide 1 to at least nucleotide 1360 but having a deletion at nucleotides 848 to 961 it was, in fact, necessary to cleave parts of this phage with parts of another phage, 293-118/37, in order to prepare the gene which was complete and suitable to allow expression of preprorennin.

Thus at 16 January 1981 the patentees had not prepared a gene that would allow expression of preprorennin and therefore the theoretical indication of achieving that expression, as well as that of prorennin and rennin, by extension was at that date based on a false premise.

This, I believe, was the basic position taken by Mr Hamer at the hearing. On the contrary, whilst Mr Hacon realised that he was in trouble in securing the first priority date for preprorennin, he nevertheless argued strongly that the first priority document supports the claims to recombinant prorennin and rennin. His argument, if I understood him aright, was based on the fact, that in the first priority document, the patentees disclosed the preparation initially of 2000 phages which they narrowed down to 80, then 8, then 4 and finally one for further study. That one was 293-207 to which I have referred above. By the time of the second priority document, having realised that 293-207 did not give the full preprorennin sequence, the four phages are described as being narrowed down to two for further study. One of these was again 293-207 and the other was 293-118/37 to which I have also referred above. It turns out that 293-118/37 contains the full sequence for both prorennin and rennin and therefore, in Mr Hacon's submission, since the method of obtaining the sequence was disclosed in the first priority document, albeit that the patentees did not realise the manner in which they had reduced the invention to practice, it cannot be said that that document does not support claims to prorennin and rennin. To that extent, he argued, the admission in paragraph 10 of the EPO decision that the idea of preparing prorennin or rennin by the recombinant DNA technique was not reduced to practice by the patentees was a wrong admission.

I must say at this stage that I have great difficulty in accepting Mr Hacon's argument on this point. It seems to me that it cannot be right for a later application to be supported by an earlier application which fails in some way to disclose explicitly that which supports the principle underlying the invention. Although Mr Hacon drew my attention to the decision of Aldous J in Biogen v Medeva in this respect, I am not sure that it helps him in the way he thought. Going on to refer to the House of Lords decision in Asahi Kasei Kogyo KK's Application [1991] RPC 485 Aldous J said this:

> "It is convenient to coin words such as "enabling disclosure", but it can lead the court to lose sight of the words in the Act. Section 5(2)(a), like section 14(5)(c), uses the words "supported by". Those words suggest that there must be something firm upon which to found the claim. It would therefore seem that a mere speculation or inoperative instructions could not be a support. Neither could the formula of a

compound which could not be made. However, that does not mean that it is necessary that every part of an application must be capable of operation by the skilled man at the date of the document. What constitutes an adequate support will depend on the facts of each case. An application which describes a new principle and a method by which it is carried out will provide a proper support for a claim to the principle however carried out. On the other hand, an application which describes a better way of carrying out an old method will only give support for a claim to the better way described. The proper approach is first to decide what is the invention and thereafter answer the question posed by the section, namely - is that invention supported by matter disclosed in the priority document? It is wrong to split that question up by asking whether any part of the application is an enabling disclosure. If there is nothing enabling, then there is nothing that can support the invention. If, however, there is an enabling disclosure, it is necessary to go on and look at the application as a whole through the eyes of the skilled man, taking into account not only the practical instructions but also the suggestions and predictions."

Mr Hacon was therefore quite right to draw my attention to the fact that, in making an assessment as to whether the first priority document supports the claims, there is the need to determine what is the invention. In the decision the learned judge said that the first clue in such a determination is to be found in the title to the patent and in this case it is to a recombinant DNA encoding a polypeptide displaying milk clotting activity and precursors thereof. Moreover, from whatever angle one views the claims, it seems that the key feature of the invention must be the said recombinant DNA since without this there can hardly be invention at all.

Having decided then that the invention is in the recombinant DNA, I must answer the question "Is that invention supported by the matter disclosed in the priority document?". Mr Hacon's position on this was that, because in the first priority document there was disclosure of a method of preparing a clone containing the full prorennin sequence, there must be support for claims relating to this sequence and the corresponding sequence for rennin. To my mind this way of looking at how the question should be answered is too simplistic since it does not give due weight to what is meant by the "matter disclosed". As

I have already pointed out, out of all the clones prepared by the patentees by the first priority date they chose one, 293-207, which they thought carried the full preprorennin gene. On the basis of this they then proposed a procedure whereby genes encoding prorennin and rennin could be prepared and, ultimately, all the relevant proteins expressed. Unfortunately 293-207 did not give them what they wanted and it is only by the date of the second priority document, some $10^1/_2$ months later, that they appreciated that another clone, 293-118/37, contained the full prorennin sequence and could be used with 293-207 to give the full preprorennin sequence.

I am compelled, therefore, to the conclusion that it is only at the second priority date they had disclosed matter which would support claims to the invention which, as I have said, is to a recombinant DNA encoding a polypeptide having milk-clotting activity. In so finding I fully accept that 293-118/37 was one of the clones prepared by the method disclosed in the first priority document but, to the extent that it was not so identified nor its significance appreciated, I cannot accept that its mere existence provides support for what the patentees claim at that date.

In whatever way I look at the approach laid down by Aldous J, I arrive at the same conclusion. Referring to the words "supported by" in section 5(2)(a) he says that they suggest that there must be something firm upon which to found the claim. He goes on to say that it seems that a mere speculation or inoperative instructions could not be a support. In the first priority document of the present case, a man skilled in the art following the specific instructions would find that they are inoperative when it comes to achieving the object of the invention. After that, whilst he may backtrack on what the patentees had done, it is a matter of some speculation as to whether he would achieve anything at all. This is consistent with paragraph 7 of EPO decision T81/87 where it says "no reliable synthetic approach was available to provide a particular DNA for prorennin or otherwise known compound, let alone for preprorennin of unknown composition at the date of the priority document". Again, looking at the approach of Aldous J to enabling disclosure, leads me to the same conclusion that the patentees are only entitled to the second priority date, namely 1 December 1981, for their patent and, because of this, that the Unilever document is relevant under section 2(3).

Before coming to a consideration of the content of the Unilever document and hence its relevance against specific claims of the Patent in suit, I note, in passing, that this too has been the subject of oppositions in the EPO. Mr Hamer brought it to my attention that the end result was that certain claims were allowed whilst others were not. However, since Mr Hacon, when I pressed him, said that for the purposes of the hearing he was not seeking to argue that Unilever and Celltech were not entitled to their priority dates, I take it that he was also not denying that their priority documents present enabling disclosures and I will proceed in that light.

Unilever relates to recombinant DNA and plasmids comprising specific structural genes of mammalian origin coding for the various allelic and maturation forms of preprochymosin, particularly those of bovine origin, and the use of the recombinant plasmids to transform microorganisms in which the genes are expressed. The maturation forms disclosed are prochymosin, chymosin and pseudochymosin, the latter being of no interest in respect of the claims of the patent in suit.

Pages 7 and 8 of the Unilever application describe 11 essential steps whereby the cloning vehicles containing the structural genes encoding the various allelic and maturation forms of preprochymosin according to the invention are produced. A slightly fewer number of essential steps are described on pages 9 to 13 of the patent in suit although it must be said that closer inspection shows the two processes to be very much the same, the greater number of steps in Unilever being explained largely by the fact that they introduced an initial screening of their clones following poly-dC-tailing and insertion into a plasmid. Specifically the two first steps in both are identical and steps 3, 4, 5 and 6 of the patent in suit identify with steps 8, 9, 10 and 11 of Unilever. Pages 8 to 18 of Unilever go on to describe, in detail the culturing of E. coli cells containing recombinant plasmids followed by the detection and isolation of the proteins in question.

This being the case and because I have decided that the Patentees are entitled only to the priority date of 1 December 1981, I have come to the conclusion that all of claims 1 to 10 are anticipated by the Unilever document. Claims 11 to 16 and 20 are claims directed to very specific features of the patentees' work which are not found in the same terms in

Unilever and may survive depending on what I decide in respect of inventive step. Claims 17 to 19 are new claims inserted for the first time as part of Set A and about which there was some argument concerning whether I should admit them to the proceedings. I will deal with them later on in the decision but my initial reaction, in so far as I can understand them, is that they also, in the main, are anticipated by the Unilever document.

I will now turn to the matter of inventive step and, whilst I could limit my consideration to those claims which I have not found to be anticipated by Unilever, it would seem more appropriate in the context of the manner in which the case has been argued, to consider what the patentees have done as a whole in relation to the prior art and then decide what, if anything, is inventive.

This brings me to the point where I must consider the suitability of Dr Neuberger as an expert witness in this case and, therefore, the extent to which I can regard his evidence as relevant to the issues involved. It is evident from exhibit MN1, his curriculum vitae, that Dr Neuberger is a person of some eminence in the field of, what I shall call loosely, genetic engineering. I do not believe for one moment that Mr Hacon attempted to deny this at any point in the hearing. What, however, he wished to question was whether Dr Neuberger had the relevant gene cloning experience in the period up to 1981 for his evidence in this case to be regarded as credible. It was clear from cross-examination that during the period 1979 to 1981 Dr Neuberger's main publications were in the field of Klebsiella, although they reflected only part of his work carried out prior to early 1979. There is no doubt that Dr Neuberger was involved in gene cloning in 1980 in respect of an immunoglobulin heavy chain gene but, on his own admittance, in 1980 and up to January 1981 he had no experience directly related to rennin.

Dr Neuberger's cloning experience involved using what he called the "established procedures". Mr Hacon, at the hearing took him through these procedures as outlined in paragraphs 12.1 to 12.10 of his written declaration with reference to such problems as obtaining a complete messenger RNA and the corresponding full cDNA, the size of the loop obtained in going from a single to a double strand of DNA and the insertion of the cDNA into a plasmid vector.

Whilst I could go into this in much more detail I have to say that at all points, both in his written declaration and under cross-examination, Dr Neuberger struck me as being a very knowledgeable and fair witness. There was to my mind no attempt on his part to avoid giving a less than full answer to a question or to claim experience in a particular area when he had none. I am firmly of the view that his account of what would have been known in the art about gene cloning in 1981, backed as it was by reference to numerous journal articles available to research scientists at this time is both fair and accurate and I will take it into full consideration in coming to my decision on the issue of inventive step. At the same time I will also bear in mind the further points which Mr Hacon put to me that Dr Neuberger must be regarded as more than an ordinary man skilled in the art and that there is no evidence which indicates whether the problems associated with chymosin are similar to those associated with immunoglobulin with which Dr Neuberger had been concerned. I will add here that, if they had so wished, the patentees could have put in evidence of their own which, of course, might have blunted the effect of Dr Neuberger's evidence. The fact that they chose not to might be said to have weakened their case at this point.

On the inventive step issue, Mr Hacon, helpfully in my view, set out the questions I should ask in coming to my decision. He put them in these terms:-

> "In other words, what one has to do is this, and this really is the Windsurfing formula {Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd. [1985] RPC 59. - my addition}. You look at the prior art; you look at the invention: could the skilled man -- or in this case it is agreed the skilled team -- have got from A to B without inventive faculty? The only quibble, and it is an important quibble, I would have with that formulation as done through Dr Neuberger is of course that it is not enough just to clone the DNA he refers to but to express that DNA to get prochymosin. The relevant question is: In January 1981 could a team skilled in the art have performed the invention, that is could they have obtained prorennin by growing cells containing recombinant DNA material which are cells capable of producing prorennin and where such prorennin can be cleaved to give active rennin? Could they have done that? And, of course, very importantly, would they have done that?

> If a skilled team could and would have done it in January 1981, the claims are obvious. If the skilled team either could not or would not have done that in 1981, the claims are not obvious."

It is, I think, instructive at this point to look at what the patentees did by reference to their own patent specification. In that way it will be possible to come to a conclusion about whether a skilled team, taking into account what was known in the art, could and would have done what they did in 1981.

As I have already indicated rennin is important commercially to the extent that a process for producing it more cheaply and easily than from natural sources would be extremely valuable. There is no doubt from the opening two pages of the specification, that the objective of the patentees was to provide such a process together with the essential materials whereby that process would work. To achieve that objective they turned their attention to recombinant DNA techniques which, at that time, were becoming established and were being used in other areas for the similar objective of achieving volume production of desirable polypeptides some of which, up to then, had only been obtainable in relatively small amounts from natural sources.

On page 4 of their patent this paragraph is to be found:-

> "Thus, broadly, the present invention provides a method of obtaining pre-prorennin, prorennin and rennin by growing cells containing genetic material obtained from recombinant DNA material and capable of expressing preprorennin, prorennin and rennin, respectively."

This paragraph, to my mind, is a useful summary of how the patentees saw the attainment of their objective.

The method they chose to obtain the desired polypeptides is outlined in general terms on page 9 to page 13 of the specification and it is useful to quote the paragraph commencing

at line 18 on page 9 if only to illustrate how they perceived the techniques to be used in the method:-

> "The starting point for obtaining the cells of the present invention is the use of recombinant DNA techniques **known in the art** (my emphasis) to obtain the genetic material desired and to insert it into the host cell, after which the host cell is cloned."

Seven essential steps are then outlined on pages 9 to 13 of the specification as follows.

The first involves the obtaining of messenger RNA of the preprorennin gene from a tissue source. In this case the tissue source is the fourth stomach of calves for the reason that rennin is found there in pre-ruminant calves. How the messenger RNA can be obtained is described by reference to two papers published in 1977 and 1975 respectively. Having obtained the messenger RNA this is converted in a second step to double-stranded DNA by "conventional means". Methods of doing this are mentioned by reference to papers in the period 1976 to 1979.

The third step involves the addition of synthetic linkers to both ends of the double-stranded DNA as for example by the use of Hind III or Eco R1 synthetic oligonucleotide using "conventional methods" as described in various papers published in 1977 and 1978. In a fourth step the DNA molecule from the third step is integrated into the chromosome or attached to a vector which can be a plasmid, virus or cosmid. Prior art vectors are described, as are techniques for the procedure, and are disclosed in the papers relating to the third step and other papers published in 1974 and 1977.

In a fifth step, the recombinant DNA molecule can be introduced into the cytoplasm of the host cell using "conventional procedures" described in papers from 1970 to 1979. The correct clone for introduction may be recognised using techniques published in 1978 to 1980.

The final steps relate to the cloning of the modified host cell followed by the expression of the polypeptide sought. Expression can be optimised by the use of promoters that are active

in the host cell, a suitable promoter in the case of E. Coli being the lactose operon promoter described in papers published in 1980.

These, then, are the conventional steps followed by the patentees with the intention of producing large amounts of rennin, prorennin and preprorennin for use in cheese making.

Following this discussion specific examples are given, in detail, of the expression of all three proteins in E. Coli. In addition, beginning at page 46 of the specification, is a specific example of the expression of all three in S. cerevisiae.

From page 29 of the specification the amount of preprorennin produced in E. coli cells is about 600 molecules per cell. In a standard assay the same strain produced about 100 molecules per cell of active rennin or an active fragment of rennin capable of clotting milk. As far as I can see, whilst assay procedures are used to determine amounts of the proteins obtained in other parts of the specific examples, no actual figures, other than those quoted above, are specified. I note, in passing, that the amounts obtained by Unilever were reported on page 18 of their specification as varying from 10^3-10^7 molecules/cell.

This then is what the patentees did and against this background I must return to the questions posed by Mr Hacon. Is this, by 1981 what a skilled team could, and would have done?

There is no doubt in my mind that faced with the objective of preparing commercial amounts of rennin by a route other than the known one, which relied on natural sources, they would have turned to consider the use of recombinant DNA techniques which, by the end of the 1970s, were being used increasingly to tackle such problems. As I understand Mr Hacon, I do not think that he was trying to deny this, rather his argument was that having considered the possibilities of using such techniques they would have reacted in a negative fashion largely because, at that time, rennin was thought to be too big a molecule for a successful result. Moreover there was in Mr Hacon's view no incentive for what he called a team "ordinarily skilled in the art" to tackle such a project when the only team really succeeding at that time was the Genentech and University of California team, one of the three key players in the field.

In support of these arguments Mr Hacon referred to the history of the work that was done in the late 1970's that led to the expression of proteins in bacterial host systems. Very briefly that history started with the production of somatostatin, a 14 amino acid protein, in 1977. In 1978 rat growth hormone and proinsulin were attempted. Genentech had successes in 1979 with two chains of human insulin and human growth hormone, the latter being a significant step forward since it was 191 amino acids long. In 1980 Professor Weismann's team in Zurich reported the cloning and expression of a polypeptide with leukocyte interferon activity but, although they had a polypeptide of 290 amino acids long, it was not certain that they had the full clone. Also in 1980 Genetech cloned and expressed human fibroblast interferon in E.coli; that was 166 amino acids long. Then came the patentees work in 1981 with 365 amino acids followed in 1983, although the work was done earlier, by Genentech's work on t-PA, which was 527 amino acids long. Factor VIII, some 2000 amino acids long, followed in 1984. Thus it is apparent that, as time went by, there was an increase in the size of protein it was possible to clone.

During cross-examination Dr Neuberger agreed that the size of the protein was a factor contributing to the problems of achieving the desired result but, in his view it was not a dominant factor. In so far as it was a factor, the resultant problems were that the protein obtained might not be precisely as desired, that is it may not have folded into an active configuration, and that the protein might not be expressed at a suitably high level to be of any commercial use. As I understood Dr Neuberger both of these problems were also possibly the result of expression in E. coli and in his opinion if they were to be overcome, particularly in respect of larger and larger proteins of mammalian origin, the real challenge in 1981 was to get out of E.coli into different expression systems.

This was, of course, also the position taken by Mr Hamer. In his submission, once recombinant DNA technology had become known, it was obvious that people could not start off on day one producing all the polypeptides that could usefully be produced. There would probably be a balance between producing the easier ones and the more lucrative ones. As for rennin he argued that there was no technical reason why the technology should not be tried, particularly as its sequence and that for prorennin were both known and there was no

trouble obtaining the messenger RNA as a starting product. From a commercial point of view it would depend on the availability from natural sources.

It was his opinion that it was only a matter of time before somebody chose to prepare rennin by genetic engineering and the fact that four companies succeeded within a few months of each other without any suggestion of particular difficulty pointed to the fact that it was a very obvious thing to do.

With reference to Dr Neuberger's evidence he submitted that it was clear that, working in E. coli, one would expect to get a low level result. It was the obvious way to obtain a result, but not necessarily a commercially useful result. To this extent, then, what the patentees had done was a failure. They had not produced a commercially viable quantity of rennin because they had been following standard procedures with non-inventive manipulations, as required, when what they should have been looking for was an expression system that would have allowed them to achieve their objective.

That they had been following standard procedures was in Mr Hamer's view apparent from the patent in suit. Each stage of the process, as I have already remarked, is described in relation to prior art procedures with the implication that any of the known ways will do. If there was a problem, workers in the field would look up the literature and see if there was a different way around it. People would have their own pet methods, as was made clear in Dr Neubergers evidence, but if something did not work it was always open to try a different route that was within the standard techniques.

As to the question of the incentive to produce rennin by recombinant techniques, Mr Hamer drew attention to what he considered to be the situation prevailing in the art at the time. In his opinion, in what was a newish area, it was only to be expected that there would only be a few key players. Much of the early work was carried out by academics but it was inevitable that big organisations such as Genentech were going to take centre stage when the commercial possibilities became apparent. In the case of rennin the fact that nobody produced it by recombinant techniques until 1981 was not, in his view, because they thought it to be impossible but because there was not a sufficient commercial incentive. When it

seemed a commercially sensible thing to do four teams decided to do it and this, he submitted, suggested that they all thought they could do it, otherwise they would not be trying. In any case, taking into account the time taken to carry out such work, rennin fitted in to the early history of recombinant DNA technology.

As to precedent cases that I should be aware of Mr Hamer brought my attention in particular to the Court of Appeal decision in Genentech Inc's Patent [1989] RPC 147, the Windsurfing case that I have referred to earlier and the case of Chiron Corporation v. Organon Tekina [1994] FSR 202. I do not think that I need to go into all the detail of the argument he was making in respect of these decisions as, to some extent, they were being raised as examples which set out the approach to matters of inventive step. Suffice to say that Genentech is obviously a key decision in the biotechnology area, dealing as it does with the approach of a skilled man in a situation that has similarities to the present, Windsurfing sets out what Mr Hacon called a formula for deciding whether an invention is obvious and Chiron is another biotech decision but dealing, in Mr Hamer's opinion, with an invention overcoming a problem of a scale far in excess of any overcome by the present invention.

With this in mind then I will return to Mr Hacon's two questions, namely, by 1981 would and could a team skilled in the art have performed the invention. I have no doubt that the answer to both of these questions must be "yes", largely for the reasons advanced by Mr Hamer.

A realistic assessment of the art up to about 1981 would seem to suggest that a standard procedure for the cloning and expression of mammalian proteins in bacterial host systems had become established. In the nature of things it was clear that the standard procedure would not always work satisfactorily or that different teams would have their favoured ways of carrying out various steps within the procedure. Either way, problems could be overcome in a way that required tenacity rather than an inventive faculty and were to be anticipated because of the unpredictability of living material. It is furthermore not surprising that, in the early days, the procedure was applied to fairly small, but vital, proteins such as somatostatin and that, following success with these, the encouragement was there to move on to larger and larger ones. There might well be a time when the standard procedure would

not work for a large molecule and that would occasion a move in another direction to solve the problem but, until that time came, and one would not know until it arrived, realistically there would be no good reason to move away from a well trodden path.

It is also to my mind not surprising that in the early days of the art there would be a few pioneer teams such as Genetech who, far from providing a disincentive to others, would have laid down very positive markers for the future once an apparently successful procedure was in place. I think it fair to say that nobody expected the future to be free of problems but, given the enormous financial rewards in prospect, it was not long before other teams joined in with every expectation of success. Thus it was that we have four teams in the early 1980's in effect competing to be the first to prepare rennin by recombinant techniques. The prize for the winner was potentially extremely large because of the use of rennin in cheese making. The problem was whether the standard recombinant DNA procedure at that time would produce commercially viable results.

I have already reviewed what the patentees did by reference to their own specification and I can come to no other conclusion than that what they did was entirely conventional at the date of the patent and led to results, in part due to the size of molecule they were attempting to express, which meant that they failed in their commercial objective. I am, therefore entirely convinced that given the desirability of preparing rennin, given the fact that prorennin and rennin had previously been sequenced and given the fact that the messenger RNA needed as a starting material was available in relatively abundant amounts, a man skilled in the art, or in this case a team, would have done what the patentees did. In support of this conclusion I must say that I can find nothing in the specification in suit which suggests that they did anything which represents an inventive departure from the standard procedure. Indeed, each step is described as being conventional by reference to the prior art, as are any possible variations within each step, and there is nothing in the specification which indicates that they have combined the individual steps in other than the conventional order. If they have done anything in any individual step that cannot be found in the prior art then, without evidence to the contrary, I must assume that it falls within the different experimental conditions which Dr Neuberger explained would be expected from different workers for this technology.

These, then, are my reasons for finding that a skilled team would have done that which was done by the patentees by 1981 and I believe that it follows that, by that date, such a team could done have what they did. The proliferation of research papers quoted by the patentees themselves in their specification points to the fact that it was not only the Genentechs of this world who were making a contribution and gaining experience in this rapidly expanding technology. The success of different groups was, of course, varied and, as I have said, the patentees did not succeed in their ultimate objective but they did manage to produce a small amount of the recombinant rennin they were seeking. Dr Neuberger explained that the detection of these small amounts was a credit to the patentee's assay techniques which I take to be a compliment related to those techniques rather than to the work leading up to their use. On the available evidence, then, I am satisfied that at the relevant date a skilled team could have done what the patentees had done and would have achieved the same result, limited as it was by the ability of the technology available at the time to deliver a result that was commercially more desirable.

I therefore find that what the patentees have done is lacking in inventive step, but before leaving this aspect of the decision, I must apply this finding to the specific claims of Set A.

Claims 1 and 2 relate to living cells containing genetic material derived from recombinant DNA material and capable of expressing preprorennin and preprorennin derived from such cells. I have already decided that the work protected by these claims is not entitled to the earlier priority date and I believe that Mr Hacon was not seeking to hang on to these claims and the other claims which relate to preprorennin for that reason. However, even if that was not the case I would find these claims as lacking inventive step based on what was known generally in the art. Even if the patentees had been the first to discover the existence of preprorennin my decision in this respect would have been the same on the basis that, since prorennin is a secreted protein, the existence of a signal peptide was reasonably predictable.

Claims 3 to 8 fail on the basis that the methods claimed are what one expects from the prior art and from the structural relationship of preprorennin, prorennin and rennin to each other.

Claims 9 and 10 in effect relate to a preprorennin cDNA and its attachment to a vector and are obvious requirements for the standard prior art procedure.

Claims 11 to 13 are very specific claims relating to microorganisms used in the process and deposited in a defined culture collection for the purposes of providing a sufficient patent disclosure. In so far as I have no evidence that there is anything special about these microorganisms other than they were the ones the patentees chose to use in carrying out the conventional process, I regard these claims also as lacking inventive step. Little, if anything, was said at the hearing by either side about the advantage, if any, of using Saccharomyces cerevisiae as opposed to E. coli as a host organism. The patent in suit does describe, in detail, a method of obtaining expression of preprorennin, prorennin and rennin in S. cerevisiae and Dr Neuberger in paragraph 16 of his written evidence postulates that this is an example of adopting a different class of host organism in order to try and improve on the yield of active protein obtained in E. coli. No details are given in the patent of the yields obtained and again I must assume, for the purposes of this case, that the use of S. cerevisiae, which I understand to have been known as an alternative organism, is an alternative conferring no particular advantage over the use of E. coli.

Claims 14 to 16 are to recombinant DNA material comprising prorennin, preprorennin and rennin nucleotide sequences respectively and lack inventive step in so far as they are the inevitable result of an obvious method.

As for claims 17 to 19 there are arguments attached to these claims concerning their admissibility in these proceedings which I have yet to address. However, in so far as I can understand them and because of the way I have approached the matter of inventive step I cannot see that they relate to inventive features any more than do Claims 1 to 16. In so far as claim 17 refers to fungal cells as host organism, a feature that did not occur in any of the claims as granted, it seems to me that, whatever other objection applies, it cannot confirm inventive step upon that claim in the absence of evidence to some unexpected effect.

Claim 20 claims the nucleotide and polypeptide pre-sequences in isolation to the rest of the sequences for preprorennin and falls for the same reasons as are directed to the other preprorennin claims above.

I have found, therefore, that all of the claims of Set A are invalid in so far as they relate to an invention that lacks novelty and/or inventive step. However, I cannot leave the decision at this point without referring to the third major issue that was raised at the hearing and that is the issue of insufficiency. I am mindful in considering this that there was some dispute about whether claims 17 to 19 of Set A should have been admitted into the proceedings and also that two further sets of claims, Sets B and C, were filed by the patentees prior to the hearing for consideration in the event that I found against them on Set A. At the outset of the hearing I decided that the correct approach would be to hear the arguments on Set A and, indeed, my decision has been based on that set. However, should I be minded to allow the patentees an opportunity to amend their patent as a consequence of my decision it would mean that they could offer Set B or Set C or indeed any other set of claims which they consider might overcome the applicant's objections and be consistent with my findings. I think that is to some extent why Mr Hamer dealt with the insufficiency argument at some length, his intention being to lay down guidelines against the event that amendments might be offered in the future.

As Mr Hacon pointed out in his opening statement, there are essentially two distinct elements to the insufficiency argument. The first centres on the fact that whilst the claims apparently are limited to rennin, prorennin and preprorennin, the description at the top of page 64 of the specification makes clear that the broad term "rennin" in all three is meant to include any sequence of amino acids which clots mammalian milk. The second has to do with the amount of expression of active rennin obtained, which, in the view of the applicant, is not sufficient for the purposes of obtaining a patent.

On the first point Mr Hacon drew my attention to page 4 of the amended statement where, after referring to the page 64 definition of rennin, the applicants go on to say

"There are other enzymes, some of bacterial origin that will clot milk (see Feldman). There is no evidence of any substantial identity between these other proteins and bovine rennin, and yet claims 1 to 3 appear to cover recombinant cells which express these other proteins. There is clearly no support for this in the description, and the specification does not, and cannot, enable persons skilled in the art to produce living cells containing such recombinant DNA material. The specification therefore lacks sufficiency as required by Section 72(1)(c) of the Patents Act."

This, said Mr Hacon, is an allegation of lack of support and since we are in the post-grant phase, is not an attack open to the applicant in this case as was made clear by the Court of Appeal in Genentech [1989] RPC 147. I must say at this point that if Genentech was the only precedent decision, I would have no hesitation in readily agreeing with Mr Hacon but both he and Mr Hamer brought my attention to the recent decision in Chiron [1994] FSR 202 as a means of looking at the insufficiency argument in a manner which would support their respective views.

In the Chiron case , which was a biotech case relating to the hepatitis C virus, Aldous J, whilst not referring directly to the decision in Genentech, reached a similar conclusion that was very much in line therewith but along the way had to take into account an argument that Mr Hamer saw as attractive in the present circumstances. I think that I can best set out the argument by reference to page 242 of the decision where the learned judge says:-

"The defendants are right that the specification does not provide sufficient instructions to make everything falling within the claims, but that is not a requirement of the law. It follows that the defendants' submission can only succeed if the claims, such as claim 1, claim more than one invention and one of those inventions cannot be performed.

Section 125(1) states that an invention should be taken to be that set out in the claims. However, sections 125(2) and 14(5) and (6) make it clear that a claim can contain more than one invention.

It is accepted law that a patent can be granted for improvements on and for selections from an earlier granted patent. Thus a claim may include within it a large number of other inventions that could be made. That does not mean that the earlier patent discloses and claims more than one invention. In this case the invention is based on the discovery of the sequence of HCV and claim 1 is to a new class of chemicals which relate to HCV. Their connection is set out in the patent on pages 27 to 31.

If the defendants' position is sound, I cannot see where a line can be drawn between claim 1 relating to one invention and claim 1 relating to a very large number of inventions consisting of each polypeptide within the class defined by the words of the claim. Thus if the defendants are right, claim 1 relates to hundreds if not thousands of inventions. I do not believe that to be a right conclusion.

The defendants' complaint is that the claims are so widely drawn as to cover polypeptides which the plaintiffs have not discovered and did not know how to manufacture. In essence, the complaint is that claims of the width of claim 1 are not properly supported by the description. Unfortunately, such a submission is not available under section 72. Therefore the defendants attempted to persuade the court that the claims relate to more than one invention and the specification is insufficient. Despite the attractive way that those submissions were advanced before me, I do not believe that section 72(1)(c) can be the suggested vehicle for the judicial massage that the defendants would wish. The equivalent of that section is being applied by many European countries, some of which have in the past had a different attitude to the effect and ambit of claims. It is therefore important that the effect of the law is, in so far as possible, the same in those countries as in this.

I reject the defendants' submission that claims, such as claim 1, relate to more than one invention. Such claims may include within them other inventions, but only claim one inventive concept and one invention."

Clearly, Mr Hacon saw this decision as supportive of his position in so far as, in his view, there is only one inventive concept which he described as making chymosin and prochymosin

by recombinant DNA techniques using a bacterial host. That being the case the argument raised by the applicants was one of lack of support and, as Aldous J had made clear, this was not an argument that was available under section 72.

Mr Hamer, on the other hand, largely I think because of what I have called the page 64 definition, saw the claims as relating to more than invention, the first being to rennin and its associated polypeptides and the second to other polypeptides such as proteases having milk-clotting ability. In his view, therefore, because there was not a sufficient description of the separate inventions in the claims, the insufficiency argument was real and was not a lack of support argument in disguise.

In this instance I am not persuaded that Mr Hamer is right. I have said previously that in my view the key feature of the invention, or to put it another way, the inventive concept, is a recombinant DNA encoding a polypeptide displaying milk-clotting activity. To my mind this is the single concept that underpins all the claims, even when the page 64 definition is taken into account and, therefore, Mr Hamer's argument fails for the same reasons that were advanced in the part of the Chiron decision that I have quoted. I therefore find that the first element of the insufficiency argument fails because, in essence, it is an argument relating to lack of support and that is not available under section 72.

As to the second element of the argument I do not believe that I need to spend much time in justifying my conclusion that this too fails in establishing insufficiency. It is true that the specification does not describe the expression of rennin in what might be called commercial amounts. However, it does tell a skilled worker how to obtain some sort of result and to that extent, in my view, the description must be sufficient. Indeed, in addressing the matter of inventive step with reference to Dr Neuberger's evidence Mr Hamer said this:-

> "His only reservation was whether you produced a commercial result - that is the witness. I agree with my learned friend that that is not the test for obtaining a patent. You do not have to produce a commercial result. What you have to do is show how to produce something. Even if it is in minute quantities, you can claim it. For the

purpose of obtaining a patent, that is fine. It is unfortunate if the claim is such that it covers a commercially viable way of doing it, but there it is."

This being the case I find against the applicants on the second element and hence against them entirely on the whole of the insufficiency argument.

I must now, before concluding my decision, return to the subject of the amendments that have been offered in these proceedings. The history of the way in which Sets A, B and C were offered is set out in the early part of this decision. All I would add by way of further explanation is that Sets A and B were advertised whereas Set C, which was offered only about a month before the hearing, was not.

There was considerable discussion at the start of the hearing as to which set of claims was to be considered. Mr Hacon explained that he proposed to argue on the basis of set C to which Mr Hamer took exception on the grounds that the applicant was seeking the revocation of a specific set of claims, that set A was now proposed unconditionally, and that the patentee could not now come along and propose a plurality of amendments.

At that point I understood Mr Hamer's main concern to be that he had a right to know what the target was at which he would have to aim in his submissions and I agreed with him. Consequently, I ruled that, since the set A claims had been offered unconditionally, the hearing should proceed on the basis of this set of claims.

I think that I perhaps misunderstood Mr Hamer because, at a later stage in the hearing, he returned to the issue of amendment of the claims at some length and it became clear that his main concern was the question of whether the Comptroller's discretion should be exercised to allow claims 17-19 of set A to be introduced and whether any further amendment beyond set A should be allowed in the event that I were to find that set invalid.

In developing his argument Mr Hamer carefully took me through the case law setting out the considerations which govern the exercise of the Comptroller's discretion to allow amendment. I do not think it necessary for me to refer in detail to Mr Hamer's submission

because Mr Hacon did not challenge the broad tenor of Mr Hamer's argument which was that the patentee has to put all of the relevant facts before the Comptroller and show the utmost good faith in all respects. The dispute between the parties hinged on what evidence in support of his request to amend the patentee is required to put into the circumstances of the present case, and at what stage in the proceedings.

On the general question of amendment, if the patentee had been seeking amendment under Section 27 of the Act, the filing of Form 14/77 requires the patentee to give reasons for seeking the amendment. If these reasons are not entirely satisfactory, the Comptroller will ask for further explanation and, in deciding whether to exercise discretion, will take the patentee's conduct into account. Of course, when a request to amend under Section 27 is advertised, an opponent may come in who may shed further light on the patentee's conduct.

The position with regard to seeking leave to amend under Section 75 in revocation proceedings is different because there is no requirement placed upon the patentee to give reasons for seeking amendment. It was common ground between Mr Hamer and Mr Hacon that, following the judgement of Falconer J in Osterman's Patent (1985 RPC 579), there is a presumption that amendment is offered with a view to meeting the grounds of revocation. Although this point was not argued before me, it seems to me to follow that this must also be accompanied by a presumption that the patentee is acting in good faith because, to do otherwise, is to suggest that the patentee should have sought to amend his patent at an earlier stage under Section 27.

The manner in which requests to amend in revocation proceedings are dealt with in the Patent Office is set out in paragraph 72.11 and the following paragraphs of the Manual of Patent Practice; briefly an examiner will consider whether the proposed amendments prima facie are allowable, but not whether they meet the alleged ground of invalidity. Amendment is frequently offered at the counterstatement stage and, if the Comptroller had good reason to believe that the patentee was not acting in good faith, I would not exclude the possibility that the Comptroller would ask the patentee for further explanation; I am not aware that this has ever happened largely, I presume, because the applicant for revocation may well have seized on the point already. If the applicant for revocation does indeed wish to argue that discretion

to allow amendment of the patent should not be exercised by the Comptroller, then this should be included in the pleadings. The Comptroller normally will decline to consider the question of discretion to amend as a preliminary issue because experience has shown that, in most cases, it is not possible to decide the matter without a full hearing of all of the arguments. On the other hand, if the applicant for revocation can make out a strong prima facie case that the patentee has not acted in good faith and there is a strong possibility that the full revocation proceedings with the filing of evidence and eventual hearing might be avoided, then it would be appropriate for discretion to be taken as a preliminary matter.

Returning to the circumstances of the case before me, the applicants did raise the question of discretion to amend, particularly with regard to claims 17-19 in their amended statement. They did not follow this up nor, prior to the hearing, did the applicants give the patentees good reason to believe that they faced a serious challenge on the question of discretion. Indeed, by agreeing to proceed prior to and at the hearing on the basis of set A of the amendments filed with the counterstatement, it seems to me that, with the possible exception of claims 17-19, the applicants were accepting that the patentees had acted in good faith and that the presumption set out in Osterman's patent was satisfied; if the applicants had wished to argue that the patentees should be denied any chance to amend on the ground of discretion, then they should have challenged set A in toto.

I have reached my decision on the basis of the Set A claims and I have found them all to be lacking either in novelty or inventive step. Claims 17 to 19 have caused me some concern as being claims that do not go strictly to meeting the grounds of revocation. Had they been so minded the patentees could have instituted amendment proceedings under Section 27 during the course of which these claims could have been considered properly. As it is they have been considered in the present proceedings and, had I found the patent including the set A claims to be at least partially valid, I would have invited the patentees to provide evidence as to why I should exercise discretion in their favour in respect of these claims.

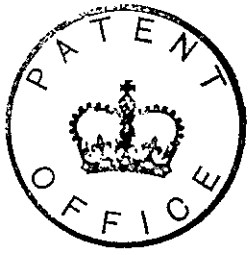
The question which now arises is whether I should allow the patentees any further opportunity to seek amendment of the patent. I believe that it is clear from my approach to the issue of inventive step that I have come to the conclusion that what the patentees did

overall was not inventive and I do not see a saving amendment. Nevertheless, I was not addressed on the Set B and Set C amendments and, despite Mr Hamer's arguments, I am not persuaded that there is a prima facie case that the patentees' have not acted in good faith and should be denied an opportunity of seeking further amendment; Mr Hacon accepted that the patentees may have jumped the gun in proposing alternative amendments but, in the circumstances of this case, I do not believe that this should be held against them.

I will therefore allow the patentees two months from the date of this decision in which to submit amendments which meet my findings and any evidence they wish going to why I should exercise discretion in their favour, and this should be copied to the applicants for revocation. The applicants will then have two months in which to submit comments on the amendments and any evidence. At the end of that period I shall give further directions as to the further conduct of the proceedings or, if no further amendment is offered by the patentees within the two month period I have allowed, I shall issue a further decision ordering that the patent be revoked.

I shall deal with the matter of costs in my final decision.

Dated this 23rd day of June 1994



P J HERBERT
Superintending Examiner, acting for the Comptroller

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