EXHIBIT 5
Part 2 of 2

96. The File contained some rather indistinct photocopies of the results of SDS-PAGE experiments, detailed notes explaining and analysing the experiments, and some conclusions. In order to understand Dr Egrie's experiments and notes, it must be understood that she had three sources of urinary EPO. The first was supplied to her by Dr Eugene Goldwasser ("Goldwasser uEPO"); the second was known as Lot 82 ("Lot 82 uEPO"); the third was known as Alpha Therapeutics ("Therapeutics uEPO").

97. In one experiment, Dr Egrie recorded that CHO rEPO and Lot 82 uEPO had the "same size, although CHO is very heterogeneous", that "Goldwasser uEPO had a lower molecular weight than Lot 82" uEPO, and that "Therapeutics uEPO is... same size as CHO + Lot 82". Dr Egrie recorded the result of a second experiment showed that Goldwasser uEPO and Lot 82 uEPO again had an apparent "MW difference". In relation to COS rEPO, she expressed the conclusion that:

> "Recombinant monkey and human EPO produced by COS cells have the same molecular weight as native urinary EPO [Goldwasser's [urinary] EPO]. This result indicates that the recombinant EPO is glycosylated to the same extent as the native protein."

98. In further conclusions, she stated that "size of Gene's standard [i.e. Goldwasser urinary EPO] ~ = size of COS cell produced EPO as was seen in the prior section IV" and that "size of CHO-cell material is larger than COS or Gene's standard" and that "CH is ~ to Lot 82 EPO".

99. On any fair reading of the File, it seems to me that, at least in Dr Egrie's view, the position was tolerably clear and was as follows. If one confined oneself to comparing recombinant EPOs with Goldwasser uEPO, CHO rEPO had a somewhat higher molecular weight than urinary EPO, but COS rEPO had the same apparent molecular weight as urinary EPO. On the other hand, once one extended the comparison to two

other urinary EPOs, namely Lot 82 uEPO and Therapeutics uEPO, CHO rEPO had the same apparent molecular weight as those two urinary EPOs.

100. Amgen can point to a small degree of latitude in the views expressed by Dr Egrie in the File, in the sense that she has indicated that different EPOs performed approximately the same, and that some EPOs were more heterogeneous than others. However, it does not appear to me that there is much room for disputing the above summary of her conclusions as recorded in her notebooks, and indeed in the File, in 1984. Further, the notion that she formed the views I have described is consistent with subsequent evidence of her views, to which I will shortly turn.

101. On the basis of the File, and in particular Dr Egrie's views as expressed therein, it appears clear that:

(1) If one confines oneself to Goldwasser uEPO, then:

(a) the statement in Example 10 that COS rEPO had a "slightly larger" apparent molecular weight than pooled urinary EPO is incorrect: they ran the same on SDS-PAGE;

(b) the statement that CHO rEPO had a higher apparent molecular weight than urinary EPO is correct.

(2) If one includes Lot 82 uEPO and/or Therapeutics uEPO, then:

(a) the statement about the performance of COS rEPO remains inaccurate;

(b) the statement about CHO rEPO is no longer reliable, because it has the same apparent molecular weight as some urinary EPOs.

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102. Mr Borun said in his evidence that, although he had plainly received the File, he does not believe that he read it before he prepared the fourth US Patent application. I do not accept that evidence. First, it seems to me inherently unlikely that he did not read documents, for which he had specifically asked, as I find he did. Secondly, I consider it is very likely that Mr Borun would have appreciated that the File was, to put it at its lowest, likely to be of interest on one of the main aspects of the Patent application which he was then concerned with drafting, namely the last three paragraphs of Example 10 in the fourth Patent application (which was submitted some four weeks after he received the File). Thirdly, Mr Borun said that (not surprisingly) it was his practice to read documents sent to him by a client in relation to a patent which he was drafting. Fourthly, there is no suggestion of his having received any other documents relating to experiments carried out by or on behalf of Amgen in relation to the performance of the various EPOs on SDS-PAGE, a topic specifically dealt with in the first paragraph he was drafting around this very time. Fifthly, the information contained in the File was of particular potential importance, because Mr Borun wanted to be able to persuade the USPTO that there was an identifiable distinction between rEPOs made in accordance with the teaching of the Patent, and prior art urinary EPO.

103. So far as Mr Borun's denial that he read the File in 1984 is concerned, I am unconvinced by it. He did not strike me as a reliable witness. He tried to avoid answering questions which presented him with difficulties. He was argumentative. He put forward explanations which were inconsistent with evidence given in earlier proceedings (and in particular the US infringement proceedings). He tried to avoid answering questions about error (a) by seeking to deflect attention to the latter part of the first paragraph. He mentioned for the first time facts which one would have expected him to raise earlier, particularly bearing in mind his close connection with the case and his knowledge of the legal issues. Further, on more than one occasion, Mr Borun suggested that Dr Egrie "would agree" with the contents of the first paragraph of Example 10. Not only does that seem to me very hard to accept in light of his acceptance that the contents of the File are inconsistent with some parts of that

paragraph, but it is also hard to reconcile with the fact that he also accepted that Dr Egrie would have been unlikely to depart from the views expressed in her notebooks.

104. In connection with the File, Mr Borun suggested that he must have had another source of information because otherwise he could not have known the designation "E.C.3.2.1" which was inserted in the first paragraph. He mentioned this point of his own initiative more than once, without being asked about it in cross examination. Further in his deposition in the US infringement proceedings he had said that he thought that he may well have looked up the designation himself. I accept that, particularly in connection with matters which occurred a long time ago, memory can fade, and indeed can be inconsistent at different times. However, I got the firm impression that Mr Borun did not really have any significant recollection whether he had looked at the File before he drafted the fourth US Patent application, but, because he appreciated the obvious difficulty in reconciling the contents of the File with some of the contents of the first paragraph of Example 10, he sought to persuade the court (and indeed may have persuaded himself) that he cannot have read the File in 1984. Indeed, I note that, in his deposition in the US infringement proceedings, Mr Borun said that he could not say whether or not he had read the File.

105. To an extent, I suppose that it can be said to be to Mr Borun's credit, he conceded that there were at least parts of the File which were inconsistent with what he had written in the first paragraph of Example 10, although that was probably an inevitable concession. He also said that, had he read the File, he would have asked questions of Dr Egrie, in particular about the suggestion that rEPOs appeared to have the same apparent molecular weight as some urinary EPOs.

106. There is no indication in any documentation or in any oral evidence (whether given in these proceedings or in any of the other proceedings to which I have referred) which even suggests that anyone from Amgen (or indeed anyone else) gave any information or opinion in 1984 to Mr Borun which was inconsistent with that of Dr Egrie as contained in the Files. Mr Borun suggested that Dr Lin may have told

him something relevant in this connection, but, while I am satisfied that he had discussions with Dr Lin, there is nothing to suggest that he would have expressed a view, let alone did express a view, inconsistent with that of Dr Egrie as recorded in her notebooks. Again, to his credit, Mr Borun accepted that it was unlikely that Dr Lin would have said anything inconsistent with the contents of the File.

107. It is fair to say that the very fact that some of the contents of the first paragraph are inconsistent with the contents of the File could be said to give some support to the view that Mr Borun did not read it. However, the fact that the only written evidence apparently made available to Mr Borun in relation to SDS-PAGE experiments does not support all that he wrote into Example 10 in November 1994 is, in my judgment, insufficient to establish that he did not read that information. Part of what he wrote in relation to the SDS-PAGE experiments was, at the very least, arguably consistent with what was in the File, namely that the CHO rEPO displayed a higher apparent molecular weight than some urinary EPO. Apart from the possibility of his having talked to Dr Lin or Dr Egrie, there is simply no evidence of any conversation or any document from which he could have got information about SDS-PAGE. Given that, as Mr Borun accepted, it is unlikely that Dr Egrie, or indeed Dr Lin, would have said anything different from what was in the File, that point takes matters little further anyway. Accordingly, the fact that the contents of the File are not reflected in at least part of the description of the SDS-PAGE experiments in the first paragraph is quite insufficient to persuade me that Mr Borun did not look at the File, in light of the other factors to which I have referred.

108. It may not matter whether Mr Borun read the File around the time he received it and, in particular, before he filed the fourth US Patent application. If, as I think, he did read it, then, as he effectively accepted in evidence, he could not justifiably have written what he wrote in the first paragraph of Example 10 about COS rEPO, without at least talking to Dr Egrie about the contents of her notebooks, which I am satisfied he did not do. In that connection, in her deposition in the United States proceedings between HMR and Amgen, Dr Egrie did not recollect Mr Borun having had a further

conversation with her. Indeed, in his evidence Mr Borun has never suggested that he had a further conversation with Dr Egrie after receiving the File, and there is no suggestion of such a further conversation in any of the documents. There is no explanation as to why Mr Borun did not make such enquiries, and, in my judgment, he should have done so. If he did not look at the File, then it seems to me clear that he failed to do something which he ought to have done, and, had he done so, then, again as he accepts, it would have been appropriate for him to have talked to Dr Egrie before he could properly have drafted the first paragraph of Example 10 as he did.

109. Of course, I am not ultimately concerned with whether or not Mr Borun himself fell below the standard one expects of a patent agent in this connection. I am concerned with the question of whether, bearing in mind the information available to Amgen and its advisers, the first paragraph of Example 10 was drafted to the requisite standard. Strictly, I am not considering the drafting of the fourth US Patent application of 30th November 1984, but the drafting of the European Patent application filed some 12 days later. The latter point appears to me to involve a distinction without a difference: as I have mentioned, the fourth US Patent application was effectively the same document as the first European Patent application. I have reached the conclusion that, in relation to the performance of COS rEPO relative to urinary EPO in SDS-PAGE experiments, Example 10 was not drafted with reasonable skill and knowledge. Whether one looks at the matter from the point of view of Mr Borun or Amgen, the only experiments, records and expert views which appear to have existed were those contained in the File, and they showed a clear record of COS rEPO having the same apparent molecular weight as the urinary EPO upon which Amgen effectively rely, namely Goldwasser uEPO.

Error (a): 1994

110. HMR points out that there were a number of different documents and other pieces of evidence which came to the attention of Mr Borun between 1984 and 1994 and, in particular which Mr Borun read during the course of the interference proceedings and

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the Chugai litigation, in which he was involved on behalf of Amgen. That would mean that he would have perused those documents by 1991. HMR says that this evidence at least should have led him to appreciate that Amgen's own experts on the topic, and in particular Dr Egrie, continued to take, and consistently took, the view that COS rEPO manufactured in accordance with the teaching of the Patent, manifested the same, or approximately the same, apparent molecular weight on SDS-PAGE as urinary EPO.

111. First, there are Dr Egrie's notebooks, which would have included all the pages in the File, which Mr Borun accepted he would have read in relation to the interference proceedings and the Chugai litigation. Secondly, Mr Borun accepted that he would have paid careful attention to Dr Egrie's deposition and declaration of 18th March 1991 in the interference proceedings, in which she said that "the carbohydrate portion" of COS rEPO and of pooled urinary EPO "were of approximately the same size", and that urinary and recombinant EPOs "migrate identically" and "co-migrate". There was nothing else in the evidence to suggest that this conclusion was wrong, either in Amgen's view or at all.

112. Thirdly, Mr Borun saw three publications in respected peer-reviewed journals in 1985 and 1986, where most of the authors were current or previous Amgen employees, which included at least one photograph of an SDS-PAGE gel showing, and reported as showing, that COS rEPO migrated effectively identically to urinary EPO, and therefore displayed the same apparent molecular weight. Thus, in one of those papers, in *Immunobiology*, Vol 172, page 213, of which Dr Egrie was the lead author, it was stated in the abstract that:

> "By Western analysis, the recombinant and human urinary EPO migrate identically."

In the highly respected New England Journal of Medicine (Vol 316, page 73) in a paper of which Dr Egrie was also one of the authors, there was this:

"In addition, the carbohydrate portion... of the natural urinary and recombinant hormones are indistinguishable..."

That meant that the two types of EPO must have the same apparent molecular weight, because, virtually by definition, the polypeptide backbone of the two EPOs was the same, and Mr Borun would or should have understood this. In her evidence in the Interference Proceedings, Dr Egrie specifically confirmed that she stood by her views in these papers.

113. Fourthly, in the interference proceedings, a brief was submitted before US Board of Patent Appeals and Interferences, on behalf of Dr Lin, who, as I have mentioned, was being backed by Amgen, and one of the three counsel named on it was Mr Borun. On page 18 of the brief, under the main heading "Statement of the Facts", and the sub-headings "The Interference History" and "Dr Joan Egrie", there was this:

"Dr Egrie... found that COS cell-expressed recombinant EPO and the pooled human urinary EPO migrated identically on SDS-PAGE, while CHO cell-expressed recombinant EPO moved differently..."

114. Fifthly, as I have mentioned, Amgen had been applying for FDA approval for the marketing of recombinant EPO. In their IND, they had stated unequivocally that recombinant EPO and naturally occurring urinary EPO "co-migrated" i.e. displayed the same apparent molecular weight by SDS-PAGE. Mr Borun said that he may not have seen that document, and, although he did not impress me as a witness, I accept that he may not have done so. However, Mr Borun did see the PLA, which, while not referring expressly to SDS-PAGE experiments, did indicate that all the tests carried out by and on behalf of Amgen suggested that recombinant EPO was "identical within the error of the methods" to urinary EPO.

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115. There do not appear to have been other experiments, or other scientists' views of experiments, which existed, let alone which were communicated to Mr Borun, prior to the hearing before the Appeal Board, which would or even could have suggested to him that COS rEPO manifested a higher apparent molecular weight by SDS-PAGE than any urinary EPO. In other words, by 1994, there was considerably more evidence available to Mr Borun in connection with the SDS-PAGE experiments, than was available to him than in 1984. In all these circumstances, subject to any factors pointing the other way, in my judgment, he, and therefore, effectively through him, Amgen, fell below the requisite standard of skill and knowledge when they supported the first paragraph of Example 10 in its entirety, and in particular error (a), and therefore Auxiliary Request 11. It seems to me that, apart from error (a) itself, there was nothing to support the statement in the first paragraph of Example 10 so far as it related to the performance of COS rEPO against urinary EPO on SDS-PAGE, either by way of experiments or by way of any scientists views of experiments.

116. It is suggested by Mr Waugh that there may have been some sort of change of mind on the part of Amgen as to the performance of COS rEPO as against urinary EPO on SDS-PAGE during the 10 years between 1984 and 1994. I cannot accept that. First, there is nothing to support it by way of oral evidence. I appreciate that neither Dr Egrie nor Dr Lin, who do not work any longer for Amgen, have been prepared to come and give evidence, but there is no indication in any document or in their evidence, depositions or declarations in other proceedings to suggest that either of them, or that any other relevant scientist, had changed his or her views, as to the effect of any SDS-PAGE experiment relating to COS rEPO and urinary EPO. Secondly, apart from the contents of Example 10 of the Patent, as drafted by Mr Borun in or before November 1984, there is nothing to suggest that the relevant scientists at Amgen, and in particular Dr Egrie, had ever taken a view different from that which was consistently held in Dr Egrie's notebooks, in Dr Egrie's depositions, and in the papers published by Amgen scientists, including Dr Egrie. To my mind, the simple and obvious answer is the correct one: error (a) was indeed an error, and it

was perpetrated by Mr Borun at the end of 1984, and has been maintained (and where necessary relied on) by and on behalf of Amgen ever since.

117. It is further argued by Amgen that error (a) was not, even viewed on its own, due to want of skill or knowledge on the part of Amgen and its representatives, in September 1994. I accept that one must be careful before characterising an error as being attributable to want of reasonable skill and knowledge. The mere fact that an error finds its way into a patent may be due to a misjudgment or an unfortunate oversight which cannot be characterised as want of reasonable skill, just as much as not every mistake by a professional person constitutes negligence. Further, I accept that one must be careful of relying on wisdom of hindsight. This was a long and complicated patent with many factors and features, and it would, I accept, be wholly unrealistic to expect Amgen and its advisors, even taking into account the very large team who attended the Appeal Board on their behalf in September 1994, to remember every relevant fact and document which had been in their possession, or which they had seen. Nonetheless, I do not consider that this sort of consideration can exonerate Amgen from a finding of lack of reasonable skill and knowledge in relation to error (a) in September 1994.

118. First, the importance of the first paragraph of Example 10 to the protein claims of the Patent must have been apparent to Amgen, and in particular to Mr Borun, and similarly the importance of the protein claims (i.e. what are now Claims 19 to 26) themselves. Mr Borun himself said that the protein claims of the Patent were important, and it is self-evident that they were, particularly in light of the uncertainty (which even now still exist, possibly to a more limited extent) as to the validity of claims to DNA sequences. The contents of the three paragraphs were needed to justify the predecessor of Claim 19 in the original Patent application in 1984. Mr Borun and other representatives of Amgen must have appreciated during the hearing before the Appeal Board in November 1994, the vital importance to Amgen of being able to distinguish recombinant EPOs made according to the teaching of the Patent from prior art EPOs, i.e. from urinary EPO. Without such a distinction, they would

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have realised that the protein claims might not be approved by the Appeal Board, essentially because of lack of novelty.

119. Indeed, it goes further than this. It is clear that, at the hearing before the Appeal Board, attention was concentrated on the first paragraph of Example 10, both in the evidence and by reference to the terms in which what is now Claim 19 was proposed to be amended. Indeed, attention had already been focused on the first paragraph of Example 10 when the matter was considered by the Opposition Division, not least because of its potential relevance to Claim 19. Additionally, the Opponents had produced expert evidence, and in particular that of a Dr Conradt, which bore directly on this issue. I note that the Appeal Board concluded that the only evidence available to support the contention that COS rEPO displayed a slightly higher molecular weight was Example 10 itself, i.e. error (a). It seems to me that, particularly bearing in mind the duty of a patentee to be candid on this sort of issue with the European Patent Office, and the fact that the issue was one of the items in the forefront of the dispute before the Appeal Board, it does not involve wisdom of hindsight to conclude that there was a want of skill and care on the part of Amgen and its advisers when supporting the first paragraph of Example 10, and in particular the contents of error (a), in front of the Appeal Board.

120. It is also contended on their behalf that Amgen were in something of a rush when preparing the various auxiliary requests, including Auxiliary Request 11, which, it will be recalled, eventually found itself into Claim 19. While there is something in the point, I am not very impressed by it. In the first place, Amgen had overnight to consider the various auxiliary requests, and their team was very substantial consisting of many experts, including Mr Borun, Mr Brown and a number of patent lawyers. Quite apart from this, it is not as if Amgen's attention in connection with the appeal had been drawn to the first paragraph of Example 10 for the first time the day on or before which Auxiliary Requests were drafted. As I have mentioned, attention had been focused on Example 10, and in particular the performance of various EPOs on SDS-PAGE, well before that.

121. Reliance is placed by Amgen on the fact that, after the Patent had been granted in its present form, a clear copy of a page of Dr Egrie's notebooks (a page which was included in the File) was obtained showing, inter alia, the performance of COS rEPO against Goldwasser uEPO much more clearly than any copy which had been available to Amgen and its advisers in the context of pursuing the Patent applications. It is contended on behalf of Amgen that this better copy supported Amgen's case on error (a), in that it arguably showed that COS rEPO had, albeit only to a small extent, a higher apparent molecular weight by SDS-PAGE than Goldwasser uEPO.

122. In my judgment, that point takes Amgen no further forward. First, the clear copy was never made available to anyone acting for or on behalf of Amgen in connection with the drafting or the pursuing of the Patent applications: that is self evident by virtue of the fact that it only came to light after the Patent was granted in its final form. Secondly, nobody at Amgen thought that this experiment showed that COS rEPO had a higher apparent molecular weight than any urinary EPO; that is clear from Dr Egrie's notebooks, the papers published by Amgen scientists, the deposition and declaration evidence of Dr Egrie in the US, and the brief in the US Interference Proceedings. Thirdly, although this clear copy was relied on by Amgen at the hearing before me in 2001 to support the accuracy of the statement in the first paragraph of Example 10 relating to the performance of COS rEPO, I was satisfied, both from the face of the document and in light of the evidence of Professor Matsudaira, called by HMR as an expert witness, that, as Dr Egrie herself thought at the time, COS rEPO performed identically on SDS-PAGE to Goldwasser uEPO. The only evidence to the contrary was that of Professor Cummings, an expert witness called on behalf of Amgen, whose evidence on the topic I found unconvincing. While I acquitted him of intentionally misleading the court, I thought that he was partisan and had lost the detachment that one would expect of an expert witness.

123. To justify their stance in relation to error (a) as at the hearing before the Appeal Board, Amgen also rely upon the fact that evidence supporting the differential

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performance of recombinant EPO and urinary EPO was given to the Board on their behalf by Dr Strickland and by Professor Cummings (both of whom gave evidence in the action before me in 2001; Dr Strickland was also a witness in the present applications). I do not consider that that assists Amgen in relation to error (a). So far as Dr Strickland's experiments relating to recombinant EPO were concerned, they were limited to CHO rEPO: accordingly, none of his evidence was relevant in relation to error (a), which, of course, is concerned with COS rEPO. Further, he did not suggest in his evidence that he had the view, let alone that he had expressed the view, that COS rEPO would, for instance, perform the same as CHO rEPO relative to urinary EPO. So far as Professor Cummings is concerned, it is true that, in his evidence before me in 2001, he expressed the view, based on the recently available clear copy from Dr Egrie's notebooks, that COS rEPO seemed to have a slightly higher apparent molecular weight by SDS-PAGE than Goldwasser uEPO. However, I do not consider that assists Amgen. First, I had little hesitation in rejecting his evidence; secondly, his evidence was in any event based on the clear copy which was not available until after the decision of the Appeal Board.

124. Nor do I consider that the evidence given by Professor Cummings before the Appeal Board assists Amgen. He expressed the view that the SDS-PAGE experiments in the published papers to which I have referred "show that the rEPO and the uEPO samples migrate to similar regions, but they do not precisely co-migrate". To my mind, this falls quite a way short of providing any support for the proposition that one particular rEPO, namely COS rEPO, has a higher apparent molecular weight than prior art urinary EPO, particularly in light of the fact that the papers to which he referred unequivocally suggested the contrary. Further, although Professor Cummings provided a "summary of differences between rEPO and uEPO" which included the statement that "SDS-PAGE analysis shows a difference", that cannot have been the basis for justifying the statement in the first paragraph of Example 10 that COS rEPO has a higher apparent molecular weight than urinary EPO.

125. Amgen also rely on the fact that their European Patent agent, Mr Brown, of whom HMR make no criticism, was a party to the deliberations of Amgen in 1994, and indeed in relation to the European Patent generally. I do not think that assists Amgen. Mr Brown does not appear to have been asked to consider, or to have had cause to consider, the question of whether there was any support for the contents of the first paragraph so far as Amgen's own work or evidence was concerned. He was entitled to assume that Mr Borun had done a proper job in November 1984 in this connection.

126. The final point relied on by Amgen in connection with error (a) in 1994 is that a number of the Opponents before the Appeal Board did not challenge the accuracy of the statement in the first paragraph as to the relative performance by SDS-PAGE of COS rEPO against urinary EPO. I reject that argument. First, at least one of the Opponents appears to have challenged this suggestion. Secondly, it may not have been to the advantage of some of the other Opponents to challenge the statement, bearing in mind that their commercial interest could have been best served by maintaining that there was a difference between the apparent molecular weight of all recombinant EPOs and all urinary EPOs. Thirdly, given that the SDS-PAGE experiments in the first paragraph of Example 10 may only have been seen to assume centre stage importance after the formation of Amgen's Auxiliary Requests, the Opponents may well not have had much time to deal with this point or to consider the implications of Claim 19 as drafted in accordance with that request. Fourthly, it is by no means clear precisely what evidence was available to the Opponents, and the extent to which any such evidence could have been used. Thus, while it is clear that Dr Fritsch and other representatives of GI would have been aware, for instance, of the contents of the File during the Interference Proceedings in 1990 and 1991, they would not necessarily have appreciated its significance during the hearing before the Appeal Board in 1994. Further, as Mr Kitchin points out on behalf of HMR, it is far from clear that the Opponents would have appreciated that there were in fact no experiments or expert views available to Amgen to support what was said about the performance of COS rEPO in SDS-PAGE experiments. Finally, I am ultimately

concerned with the skill and care employed by Amgen and their advisers, not the conduct of the Opponents at the Appeal Board hearing.

Error (b)

127. Error (b) is based on my finding, again consistent with Dr Egrie's conclusion, that, while CHO rEPO had a higher apparent molecular weight by SDS-PAGE than Goldwasser uEPO, it had the same apparent molecular weight by SDS-PAGE as Lot 82 and Therapeutics uEPOs. On that basis, HMR argues that the statement in the first paragraph of Example 10, at least to the extent that its suggested that CHO rEPO had a higher apparent molecular weight than urinary EPO was wrong, because, while it had a higher apparent molecular weight than one type of urinary EPO, it had the same apparent molecular weight as two other types of urinary EPO. Subject to the question of whether Lot 82 uEPO and/or Therapeutics uEPO were "pooled" urinary EPO, it seems to me that error (b) is established. As I have said, that is accepted by Amgen for the purpose of the present applications, albeit that they are appealing my decision.

128. It might appear at first sight that the arguments relating to error (b) are very similar to those relating to error (a), and therefore that the same conclusion should apply, namely that, judging the matter in 1984 and in 1994, the inclusion of error (b) in the first sentence of Example 10 was attributable to lack of skill and knowledge. However, there are differences, which to my mind are not merely significant, but which lead to the conclusion that error (b) cannot fairly be attributable to lack of reasonable skill or knowledge on the part of Amgen and its advisers, including Mr Borun.

129. First, there was clear evidence in the File to support the contention that CHO rEPO did manifest a higher molecular weight by SDS-PAGE than at least one sample of urinary EPO (namely Goldwasser uEPO) and, indeed, that it did so on more than one occasion. Indeed, to that extent, unlike error (a), Dr Egrie's recorded view was

consistent with error (b). Secondly, there was plainly a reasonable basis for concluding that the other urinary EPOs, indeed those urinary EPOs which seemed to have a similar apparent molecular weight as CHO rEPO, namely Lot 82 uEPO and Therapeutics uEPO, could be properly regarded as irrelevant for the purpose of the first paragraph of Example 10. That is because the purpose of Example 10 is to found a basis for the limiting words at the end of Claim 19, and that limitation is to distinguish the recombinant EPO's claimed from prior art urinary EPO.

130. In this latter connection, there are two points. The first, and probably less significant, point is that it does not appear that Lot 82 uEPO came from a "pooled source", and it is unclear whether Therapeutics uEPO came from a "pooled source". A "pooled source" means more than one human source, and it will be noted that the relevant sentence in the first paragraph does indeed refer to "pooled" urinary EPO (whereas the limiting provision at the end of Claim 19 does not). Secondly, while I took a different view, it appears to me that it was perfectly reasonable for Amgen and their advisers to have considered that Lot 82 uEPO and Therapeutics uEPO were irrelevant because they did not in fact represent prior art EPO so far as the Patent was concerned, and that they were therefore irrelevant for the purposes of novelty, and could effectively be discarded.

131. As to this latter point, two issues arise. The first issue is the relevant priority date for the purpose of Claim 19, and in particular the closing part thereof as finally settled pursuant to the decision of the Appeal Board in accordance with Auxiliary Request 11. In light of the Opinion of the Enlarged Appeal Board in G002/98, given on 31st May 2001, it appears to me that the relevant priority date in connection with this aspect of the Patent, namely claim 19 in its final form, was 30th November 1984, the date of the filing of the fourth US Patent application, because it was only then that the teaching which formed the basis of the limitation at the end of Claim 19 was revealed in the three paragraphs of Example 10. However, I do not consider that that point was by any means clear prior to that decision of the Enlarged Board. As I see it, there were reasonable grounds for thinking that, as the closing words of Claim 19 in its

final form represented a limitation on the Claim, an earlier date, namely the date of filing of the first US Patent application could still be relied on as the priority date for the whole of Claim 19: see, for instance, the decision of the Appeal Board in G1/93 "Limiting Feature/ADVANCED SEMI-CONDUCTOR PRODUCTS" - OJ EPO 1994, 541.

132. So far as the second issue is concerned, it appears to me by no means clear whether Lot 82 uEPO or Therapeutics uEPO were part of the prior art, although I held them to be so. In this connection, it seems to me that Amgen are quite justified in relying on the fact that the Rapporteur to the Appeal Board ("the Rapporteur") relayed the view that Lot 82 uEPO was not prior art, and made that clear to Amgen. On 25th August 1994, the Rapporteur wrote a fairly detailed letter to Amgen's European patent agents, expressing the clear view that, in order to determine whether Amgen's recombinant EPO was novel, it was necessary to limit the comparison with urinary EPO obtained by "unmodified prior art methods". He went on to describe Lot 82 uEPO as having been made pursuant to a "substantial modification of the Miyake method [used to produce Goldwasser urinary EPO and was] therefore not applicable in general".

133. So far as Therapeutics uEPO is concerned, I consider that Amgen were entitled to take the view that the same conclusion applied. There is very little evidence as to how Therapeutics uEPO was manufactured, and I am not persuaded that it would have been prior art uEPO as at 30th November 1984, if the reasoning of the European Patent Office as to Lot 82 uEPO is correct. The evidence is lacking to show that it was available, other than through private or confidential sources, at the priority date even if one takes that date as the filing of the fourth US Patent application.

134. It was argued on behalf of HMR that notwithstanding the communicated view of the Rapporteur, Amgen should have suggested to the Appeal Board that Lot 82 uEPO was in fact prior art, either because it was available before the relevant priority date or (as I held in the judgment of 11th April 2001) because it represented a workshop

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modification to what was undoubtedly prior art, and it therefore also constituted prior art. Even bearing in mind the obligation of a patent agent, and indeed of an applicant for a patent, to draw the attention of the Patent Office to information or documentation which is relevant and may affect the question of the validity of the patent or some of its claims, I think that that submission involves imposing on Amgen and their advisers a much greater responsibility than is appropriate. It seems to me likely, and Amgen and their advisers were entitled to assume, that the view expressed by the Rapporteur to the effect that Lot 82 uEPO did not represent prior art and should not be referred to in relation to the Patent, was a considered and informed opinion. It was therefore a view which Amgen were entitled to accept and to rely on.

135. In this connection, while the duty of candour on an applicant for a patent and its patent agent is undoubted and important, one should not carry it too far. As was pointed out in General Tire & Rubber Co. –v- Firestone Tyre & Rubber Co. Ltd [1975] RPC 203 at 269, "It is, after all, the function of a patent agent to argue in honesty for the width of the application". More recently, Pumfrey J said in Nutrinova at [2000] FSR 831 at 835-6 that:

> "It must always be remembered that it is the task of the patent agent to exercise his skill to apply to obtain as wide a coverage for the invention which is disclosed to him by the inventor as the state of the art known to him at the time of the application would reasonably warrant."

136. Furthermore, in relation to the performance of CHO rEPO, there was additional evidence which was presented to the Appeal Board, in the form of a report on experiments by Dr Strickland. It is clear that his research, as presented, indeed confirmed Dr Egrie's research to the effect, that CHO rEPO had a higher apparent molecular weight, on SDS-PAGE, than certain urinary EPO, and in particular Goldwasser uEPO.

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137. In all these circumstances, I am of the view that the presence of error (b) in the Patent as approved by the Appeal Board is attributable to Amgen in the sense that they did not draw the attention of the European Patent Office to the performance of CHO rEPO as against Lot 82 uEPO and Therapeutics uEPO, but that their failure to do so cannot be criticised. An applicant for the Patent, using proper skill and care, could reasonably have decided, as indeed the European Patent Office itself decided, that these types of urinary EPO were irrelevant even for the purpose of comparison with recombinant EPO in the context of the experiments described in the first paragraph of Example 10, and, indeed, in light of the qualification to Claim 19 as expressed in Auxiliary Request 11. Even if Amgen had taken a different view from the European Patent Office, they were entitled to take advantage of the considered view expressed in the letter of 25th August 1994, unless it had been apparent to Amgen that the Rapporteur was under a misapprehension or was not aware of some relevant fact. There is no suggestion of that.

138. It is fair to say that there is nonetheless an argument for contending that Amgen were guilty of want of reasonable skill and knowledge in relation to error (b) in 1984 as they did not have the benefit of the letter of 25th August 1994 from the Rapporteur, or any equivalent communication from the USPTO, at the time. Despite that, I am of the view that error (b) did not involve a culpable failure on the part of Amgen in 1984. There was an arguably justifiable basis for error (b), namely that communicated by the Rapporteur in August 1994. Further, the circumstances in which error (b) was written in 1984 are, unsurprisingly, pretty unclear, and there are (and presumably were) question marks over the general availability and pooled nature of Lot 82 uEPO and Therapeutics uEPO. It would, in these circumstances, be unfair to characterise the mistake in 1984 as due to want of reasonable skill or knowledge, even bearing in mind that the onus is on Amgen.

139. HMR nonetheless point out that Amgen relied on the fact that CHO rEPO seemed to have the same apparent molecular weight as Lot 82 uEPO, and Therapeutics uEPO when it suited Amgen, and that this demonstrates that Amgen did not in fact believe

that these urinary EPOs were to be excluded from comparison with Amgen's recombinant EPO on the basis that they were not prior art. I think it is quite irrelevant that Lot 82 uEPO or Therapeutics uEPO were apparently referred to as comparators in the IND or the PLA, which were submissions to the FDA. That is because the question of whether those urinary EPOs were or were not prior art would have been wholly irrelevant to the issues before the FDA. While it is true that reliance was placed on the performance of CHO rEPO on SDS-PAGE against Lot 82 uEPO before the USPTO in the evidence of Dr Strickland on behalf of Amgen, it seems to me that, this is not necessarily inconsistent with Amgen's case. They could have been putting in this evidence merely to confirm the contention that recombinant EPO's performance on SDS-PAGE experiments was consistently very similar to the performance of urinary EPOs, irrespective of the precise source of those latter EPOs. Further, the fact that they relied on experiments against arguably non-prior art EPO in the USPTO does not of itself mean that they were in breach of their duty of candour of their duty to use proper skill and knowledge in not putting forward such evidence to the European Patent Office, or in relying on error (b) in the European Patent Office, or even in the USPTO.

Error (c)

140. Error (c) can be dealt with more shortly. Not long before the filing of the fourth US Patent application and the application before the European Patent Office, Amgen arranged for samples of recombinant EPO made in accordance with the teaching of the Patent to be sent to a Dr Yu of Yale University. This was because, according to Dr Lin, there was no one in his laboratory "with expertise in determining the carbohydrate constitution of glycoproteins". Dr Yu analysed samples of urinary EPO, and of recombinant EPO made in accordance with the teaching of the Patent, and reported to Amgen that the results of his experiments were as recorded in the second paragraph of Example 10. These results were reported shortly before the filing of the fourth US Patent application and the application for the grant of the Patent to the European Patent Office. Because no one at Amgen had expertise in the

carbohydrate composition of glycoproteins, the fact that Dr Yu's reported results were inaccurate was not appreciated by anyone at Amgen, or indeed by Dr Borun. It appears that it was only during the Interference Proceedings, namely sometime in 1990 or 1991, that Amgen appreciated the error. During the appeal process before the Appeal Board, but well before the hearing in September 1994, Amgen conceded that the experiment reported in Example 10 was inaccurate, and indeed the Appeal Board described it as admittedly "wrong and unreliable" in its decision in November 1994.

141. So far as I am aware, there has never been any explanation as to how Dr Yu can have arrived at or recorded what are now admitted to be plainly wrong figures, or, to be more precise, one egregiously wrong figure (namely the figure of 15.09 for Hexoses in relation to recombinant EPO) in his analyses. Given that nobody within Amgen had the requisite expertise, and there is no basis for criticising Mr Borun in this connection, it seems to me that it cannot be said that any employee or representative of Amgen demonstrated a want of reasonable skill and knowledge in connection with error (c).

142. However, HMR argues that that does not determine the issue of reasonable skill and knowledge in relation to error (c). First, as I have already mentioned, Dr Yu, who for this purpose could be said to be an agent of Amgen, and who is self-evidently a carbohydrate analyst of experience, had made an error for which there is no explanation and which was translated into the Patent as drafted and as initially granted by the Examining Division and upheld by the Opposition Division. HMR say that, on the face of it, therefore there was an apparent lack of skill and knowledge which has not been explained by Amgen, on whom the onus lies.

143. Secondly, HMR says this in answer to the contention raised by HMR in the 2001 proceedings that the subsequent deletion of the first paragraph from Example 10 resulted in what might at least superficially appear to be a paradoxical contention of added matter, Amgen submitted that it should have been obvious to the notional addressee or reader of the Patent that the carbohydrate analyses of recombinant EPO

in the first paragraph were inaccurate. I accepted that submission. In those circumstances, there is some apparent attraction in the argument that, in so far as error (c) is concerned, the Patent was not drafted with reasonable skill and knowledge. In effect, if one concludes that the notional addressee of the Patent would have appreciated that a particular passage was wrong, then one is saying that the error concerned is or should be obvious to the person or group of persons to whom the Patent is notionally addressed. On that basis, one must have some sympathy with the apparent logic and symmetry of the suggestion that the obverse of that conclusion is that there was want of reasonable skill or knowledge in drafting that particular passage of the Patent. If the error is obvious to the notional reader, then, at least in the absence of special facts or an explanation, it is said that it should be obvious to the actual writer.

144. These arguments have obvious attraction. However, I have come to the conclusion that they should be rejected. I am ultimately concerned with the question of whether the inclusion of error (c) involved a want of reasonable skill or knowledge on the part of Amgen and this would include Mr Borun as the individual responsible for drafting the Patent. It was positively creditable for Amgen to have taken the view that none of their employees had the skill to carry out the carbohydrate analysis in question, and no criticism can, or has, been made of them in having contracted out that exercise to an apparently competent expert, Dr Yu. It is not suggested, other than by reference to the notional addressee of the Patent, that his mistake should have been obvious to Amgen or Mr Borun.

145. There is no warrant, in my view, for equating all the components of skill and knowledge to be expected of the notional reader of a Patent to the actual writer of the Patent, even accepting that the writer under section 63(2) is treated as extending to the patentee, its employees and its patent agent. There is nothing to suggest a departure from reality when asking whether the patentee was guilty of want of reasonable skill and knowledge under section 63(2). The Statutory language and the authorities appear to require the court to take the patentee and his patent agent as it

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finds them, albeit that one obviously is entitled to expect them to be honest and to expect the patent agent to be "properly instructed" and professionally competent (see the guidance given in Chiron (No. 7) at [1994] FSR 458 at 467 to 468).

146. In these circumstances, I am of the view that error (c) did not result from want of reasonable skill or knowledge on the part of Amgen.

Want of good faith

147. In light of my conclusion so far, the contention that there was want of good faith on the part of Amgen and/or its agents primarily applies to error (a). I have concluded that, although error (b) was a mistake, it was based on a view which appears to me to have been reasonable and defensible. This is mainly because Lot 82 uEPO and Therapeutics uEPO were arguably not prior art and were therefore irrelevant. Indeed, this was a view which the European Patent Office had adopted and, indeed, had specifically communicated to Amgen in August 1994. It is also because they may not have been "pooled". HMR has never contended that error (c) involved want of good faith on the part of Amgen.

148. The contention that, when drafting and filing the fourth US Patent application towards the end of 1984, and thereafter supporting the European Patent application, particularly during the hearing before the Appeal Board in September 1994, Amgen, in particular through Mr Borun, but also through Mr Odre, were guilty of bad faith in relation to maintaining error (a), is strongly, understandably and ably pressed by Mr Kitchin on behalf of HMR. First, as at November 1984, Mr Borun had not been supplied with any evidence to support error (a), and, indeed, had been provided with tolerably clear, unequivocal and first hand evidence (namely the contents of the File) which showed that error (a) was indeed wrong. Secondly, during the subsequent ten years, and in particular during the course of the interference proceedings and Chugai litigation, a number of further documents and items of evidence came to the attention of Mr Borun which underlined that error (a) was indeed a mistake. Thirdly, when it

suited Amgen to do so, namely in the brief in the interference proceedings and in their IND and PLA before the FDA, they appear to have mounted a case directly contrary to what was said in error (a). Fourthly, the issue was not a background matter: performance of COS rEPO, as well as of CHO rEPO, as against urinary EPOs on SDS-PAGE was a matter of debate, evidence and in argument, in writing and orally, particularly before the Appeal Board. Fifthly, Amgen had an obvious motive or incentive to maintain error (a), particularly before the Appeal Board, but also before the Opposition Division and the USPTO, because, without it, there was, to put it at the lowest, a real risk that all or most of the protein Claims of the Patent would fail for want of novelty, i.e. because of an inability to distinguish recombinant EPOs, made according to the teaching of the Patent, from prior art, namely urinary EPO. Finally, HMR relies on the contention that Mr Borun was a dishonest witness, and, if not dishonest, Mr Odre was a very poor witness.

149. The factual basis and force of some of these points is unanswerable, in my judgment. In particular, it seems to me that, in and between 1984 and 1994 there was no evidence to support error (a) and increasing evidence became available to Amgen and indeed to Mr Borun, to show that it was a mistake. Further, it appears to me clear that the significance of the first paragraph of Example 10 should always have been a factor in the minds of Amgen and their advisers: it was plainly significant and it was the subject of evidence and argument in the USPTO as well as before the European Patent Office. However, the force of some of the points relied on by HMR is not quite as strong as might first appear.

150. While it was undoubtedly in Amgen's interest to maintain the accuracy of error (a), that point must not be overstated. First, at least until the mistake in Dr Yu's carbohydrate analysis was discovered, there were grounds in the Description of the Patent outside the first paragraph of Example 10 to support a novelty argument, namely error (c). However, error (c) does not assist Amgen after 1991, because, by then, they had learnt of the inaccuracy of the carbohydrate analysis. Secondly, in light of the fact that I have rejected any want of skill or care on the part of Amgen in

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relation to error (b), Amgen could still justifiably rely on the fact that CHO rEPO had a higher apparent molecular weight than what the European Patent Office had held to be the only type of prior art urinary EPO against which it had been run on SDS-PAGE, namely Goldwasser uEPO. Indeed, Amgen were entitled to rely on the evidence of Dr Strickland, to the USPTO and to the European Patent Office (including the Appeal Board), to the effect that he had carried out SDS-PAGE experiments on CHO rEPO which confirmed Dr Egrie's conclusion that CHO rEPO had a higher apparent molecular weight than urinary EPO, or at least urinary EPO prepared according to what Amgen reasonably believed, and indeed the European Patent Office believed, was the only prior art urinary EPO. There is also the point that CHO rEPO was, in practice, much more important than COS rEPO. Indeed, particularly by the time of the hearing before the Appeal Board in September 1994, it had been long apparent, as I understand it, that the manufacture of EPO in accordance with the teaching of the Patent was commercially very effective in CHO cells, but was of very limited value in COS cells.

151. While it is true that Amgen contended before the FDA that there was no distinction in the apparent molecular weight and other characteristics of recombinant EPO and urinary EPO, it does not appear to me that such a contention could fairly be said to be inconsistent with what is contained in the first paragraph of Example 10. One would not be comparing like with like. As I have already mentioned, Amgen were entitled to take the view, which may be different from the conclusion I reached but was the same as that communicated by the Rapporteur in August 1994, namely that the only relevant prior art urinary EPO was Goldwasser uEPO. Accordingly, it was proper, and consistent with reasonable skill and knowledge, for Amgen not to refer the Appeal Board to the fact that CHO rEPO had the same apparent molecular weight by SDS-PAGE as Lot 82 uEPO or Therapeutics uEPO, because they were not, on this hypothesis, prior art. On the other hand, as I have already mentioned, the fact that a particular urinary EPO was prior art was irrelevant from the point of view of the FDA. In those circumstances, it seems to me that it was quite consistent for Amgen to inform the FDA that their recombinant EPO, which would have been (or at

least would have included) CHO rEPO, had the same characteristics as urinary EPO, because CHO rEPO did indeed have the same apparent molecular weight by SDS-PAGE as Lot 82 uEPO and Therapeutics uEPO.

152. HMR's reliance on the contents of the brief in the interference proceedings plainly has greater force. The passage in question must put beyond argument the contention that, by 1994, Amgen and Mr Borun were well aware of the conclusion that Dr Egrie had reached as to the performance of COS rEPO against pooled urinary EPO. Further, when it suited Amgen to rely on her conclusion, Amgen said so. However, it nonetheless remains the case that what is stated in the brief was entirely true, and had indeed been before the USPTO, namely Dr Egrie's views on the performance of COS rEPO on SDS-PAGE against Goldwasser uEPO.

153. I turn to HMR's reliance on the performance of Mr Borun and Mr Odre in the witness box. As already mentioned, I found Mr Borun a singularly unimpressive witness. He manifested many characteristics which can be fairly relied on to support the contention that he was not an honest witness. However, I have reached the conclusion that his unreliability in the witness box was ultimately due to a combination of his being a naturally poor witness, his lack of any clear memory of what happened in 1984, his fairly selective memory of what happened in 1994, his appreciation of the apparent difficulty he had in justifying his drafting and subsequent support of the first paragraph in light of the contents of the File, the feeling of a need to justify this drafting and support, and a relatively high ability to deceive himself that what he wanted to have happened did happen. Taking into account the totality of his evidence, and the cogent criticisms made of him by Mr Kitchin, I have come to the conclusion that Mr Borun was not a dishonest witness, in the sense of giving evidence which he knew to be untrue.

154. While criticisms were advanced of Mr Odre, I do not consider that his honesty as a witness was successfully impugned either. He was a somewhat combative witness who, in common with some other lawyers, found it difficult to remember that he was

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meant to be giving factual evidence rather than arguing his clients' case. In particular HMR says he was less than honest when he refused to accept that Lot 82 uEPO had been relied on in one declaration (that of Dr Strickland) filed on behalf of Amgen in the USPTO, and this at least could be said to have been inconsistent with their case that urinary EPO was not prior art. While there is undoubtedly something in the criticism as to the way in which Mr Odre dealt with the point, I do not consider that it justifies rejecting his evidence generally. Two other criticisms of him, namely that he refused to agree that Amgen had told the USPTO that they accepted that recombinant EPO could not be precisely defined, and that he gave inconsistent evidence about the confidentiality of documents disclosed in the USPTO and in the US proceedings, do not seem to me to take matters much further. As to the former point, it appeared to me that, in the relevant submission to the USPTO, Amgen's point was that it was not possible to define in detailed and specific terms the difference between all recombinant EPOs and urinary EPO. This is not inconsistent with their case to the USPTO, or indeed the European Patent Office: indeed it is what the Appeal Board concluded in 1994. As to the second point, Mr Odre, in common with many witnesses, initially expressed a generalised view in somewhat imprecise terms, which he subsequently qualified, again in somewhat imprecise terms. Mr Odre was also criticised for his support of a patent which contained the first paragraph of Example 10, but it appears to me that the detailed drafting of the various US Patent applications was left to Mr Borun, and I do not think that Mr Odre's involvement really takes matters further, because he was not so concerned with the details himself.

155. In any event, what ultimately concerns me here, is not the honesty of Mr Borun or Mr Odre in their respective evidence, but whether the first paragraph in Example 10 was drafted in good faith in 1984, and whether it was, as it were, supported in good faith in 1994, and whether Claim 19 was accordingly drafted in 1984, and supported and re-drafted in 1994, in good faith. The honesty or otherwise of Mr Borun, or indeed Mr Odre, as a witness in the present applications can only be of indirect relevance in that connection. Even if I concluded that Mr Borun was downright dishonest as a witness, it would not establish that he had been guilty of bad faith in

1984 or 1994. However, I accept that it would assist that contention, because it would establish that he was a person who was prepared to lie, and also that he may well have been lying because he had something to conceal in connection with his conduct about which he was given evidence. While, as indicated, I do not think he gave dishonest evidence, the overall impression given by Mr Borun as a witness certainly does not assist Amgen in discharging the onus which section 63(2) imposes on them of establishing good faith.

156. I find the question of whether Amgen, essentially through Mr Borun, lacked good faith when drafting the first sentence of Example 10 by no means easy to decide. I have already referred to the reasons advanced by HMR as to why it is likely there was bad faith on the part of Amgen in 1984 and in 1994, and there is also the puzzling fact that there simply appears to have been no evidence to support the proposition embodied in error (a): that could be said to render it comparatively easy to conclude that it must have been made up by the draftsman, Mr Borun, which is pretty close to amounting to bad faith without further ado.

157. On the other hand, I do not find it difficult to believe that the original inclusion of error (a) in the first paragraph of Example 10 in 1984 was simply due to a misunderstanding or oversight on the part of Mr Borun. While I accept that it is difficult to explain specifically how such a mistake could have occurred, there are, I think, three points to bear in mind. First, one is talking about events that took place over 17 years ago, and it is not impossible that there was some sort of discussion with Dr Egrie, or some reading of the File, which led Mr Borun to have a wrong recollection or make a wrong note, which he has now forgotten or lost. Secondly, the recording of wrong facts in a document is almost always difficult to explain after the event: people make honest mistakes in all areas of life, and, after the errors are pointed out, they are often impossible to explain. Thirdly, it is not only difficult to explain an error of this sort: it is also difficult to see why it would have been included dishonestly by Mr Borun. He must have known that the US Patent application would be scrutinised and tested by the USPTO, and, bearing in mind the obvious value of

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the US Patent, if it was granted, he must have appreciated that it would be likely to be challenged and scrutinised by a number of interested parties (as indeed turned out to be the case: note the Chugai action and the Interference Proceedings). Further, if he was being dishonest, that must predicate that he knew what Dr Egrie had recorded in her notebooks about the performance of COS rEPO on SDS-PAGE, and he would have had no reason to think that she would not say the same thing in her evidence. To have deliberately included an important misleading statement in a patent application would therefore have been likely to have been appreciated by him as being something which would be very risky indeed for his clients.

158. Quite apart from this, it would have been very risky for him. As a patent attorney responsible for the drafting of the fourth US Patent application, Mr Borun would, I understand, have been liable for professional misconduct if he had knowingly included an inaccurate statement in a patent he was drafting. Although I have little doubt but that Amgen were important and valuable clients of Mr Borun's firm, and although it is not unknown for some lawyers to act over enthusiastically, even on occasion dishonestly, on behalf of their clients, this would have been a particularly risky course for Mr Borun to have taken in the present case, from the point of view of both his clients and himself.

159. Furthermore, at the time he drafted the fourth US Patent application, the important point about the protein claim so far as novelty was concerned, was that the product had "an average carbohydrate composition which differs from that of naturally-occurring EPO" – quoting from Claim 40 in its original form in the European Patent application as well as the fourth US Patent application. Ignoring error (a), Amgen had the benefit of other statements in Example 10, ironically errors (b) and (c), which appear to have supported this definition of the protein product in any event. In 1984, he was not to know that they were both mistakes, and, for the reasons I have given, he cannot be criticised for that. There would have been therefore little incentive for Mr Borun to be dishonest in including error (a) save for the purpose of seeking to lay the

ground for seeking to argue that COS rEPO was within the protein claims of the Patent.

160. In view of the terms, approved by the Examining Division and the Opposition Division in respect of Claim 20 (the predecessor of the ultimate Claim 19) the contents of the three paragraphs were (ironically) irrelevant to the claims of the Patent as granted initially and as upheld by the Opposition Division. It was only because of the decision of the Appeal Board in November 1994, that they again became relevant to the claims because of the terms of Claim 19 as approved by the Appeal Board – i.e. in accordance with Auxiliary Request 11. Perhaps a further irony is that the only reason any limiting words were required in Claim 19 was the view of the European Patent Office on the product-by-process claims, a view with which I disagree (see my earlier judgment at paragraphs 283-299).

161. By 1994, the situation had developed since 1984. There was still a significant degree of concentration on the three paragraphs of Example 10. That was because of the importance they had for Claim 19. Additionally, there was relevant evidence called by some of the Opponents, the fact that error (c) had been established and accepted by Amgen, and the body of evidence showing the views of Dr Egrie and other Amgen scientists about the performance of COS rEPO on SDS-PAGE. All of this can be said to make it difficult to understand how Amgen, and in particular Mr Borun, could have believed the information in error (a). However, there are countervailing factors.

162. First, as I have mentioned, by 1994 it was clear that CHO rEPO was commercially much more important than COS rEPO, and this ties in with the fact that no criticism could be made of Amgen in relation to their reliance on the information in error (b), particularly in view of the fact that it was accurate if the European Patent Office was correct in its view that only Goldwasser uEPO was prior art. Secondly, the evidence advanced by Amgen to support the contents of the first paragraph of Example 10 in relation to SDS-PAGE experiments, either related to CHO rEPO alone

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(as in the case of Dr Strickland's evidence) or was expressed in rather general terms, and did not, dishonestly or otherwise, support error (a), in relation to COS rEPO (and in this connection, I have in mind the evidence of Professor Cummings). Further, so far as Dr Egrie's evidence is concerned, Amgen and Mr Borun would have known the view of the USPTO. In deciding to accept the claim equivalent to Claim 19 in the form acceptable to it, the USPTO described her data relating to COS rEPO as being "at best ambiguous" and "thus.. not sufficient to contradict" what was in error (a). While I find that conclusion difficult to understand, at least on the evidence I have seen, it seems to me that it was not unreasonable for Mr Borun and Amgen to proceed before the Appeal Board on the basis that this conclusion was correct, or at least arguable. Similarly, the Opposition Division had considered that the Opponents' evidence did not show that "the carbohydrate component of [human] rEPO is identical to that of [human] rEPO.

163. In addition, although they may not have been able to use it, Dr Fritsch and GI's attorney, Mr Eisen, would have been aware of Dr Egrie's evidence, of the papers published by Dr Egrie and others, and, probably, of the contents of the File, by virtue of their involvement in the Interference Proceedings in 1991 and 1992. In those circumstances, it seems to me that it is unlikely that Mr Borun would have pursued error (a), if he knew or believed that it was plainly wrong on the basis of evidence available to the Opponents. The risks would have been very substantial, not least in light of the evidence of Dr Conradt, which he obviously had in mind in September 1994, as it was part of the opponent's evidence.

164. It also appears to me that, at least as at 1994, it is somewhat unrealistic to treat error (a) and error (b) as distinct, although it may be reasonable to do so as at 1984, and it may be appropriate to do so for some of the purposes of these applications. By 1994, the argument between Amgen and the Opponents involved a debate on the general question of whether recombinant EPO could be distinguished from urinary EPO, and it was concentrating more on CHO rEPO than COS rEPO, because it was in CHO cells, rather than in COS cells, that the claimed invention worked in a

particularly satisfactory way. Although Mr Borun and others on behalf of Amgen would inevitably have had to think about the performance of recombinant EPOs on SDS-PAGE as against urinary EPOs, it was one among many topics which had to be considered. Additionally, while it would be quite unrealistic to suggest that consideration should not have been given to the performance of different recombinant EPOs against different urinary EPOs, there can have been no question of anyone having given the sort of very detailed consideration to the nature and ramifications of error (a) that it had been given during the six days that these applications lasted.

165. In all these circumstances, albeit not without some hesitation, I have come to the conclusion that Amgen have established that there was no lack of good faith on their part, or on the part of any of their agents, when including error (a) in the first paragraph of Example 10 in 1984, or in supporting the same in 1994, or in supporting and drafting Claim 19 in its various forms, in 1984 or 1994. A finding of lack of good faith would involve a serious criticism of Mr Borun. While the allegation only has to be made out on the balance of probabilities, I must bear in mind the gravity of the allegation and also the substantial lapse of time and the inevitable fading of memories. The onus is on Amgen to establish good faith, and they have discharged it.

166. Even though I have found that error (b) was not attributable to want of reasonable skill and knowledge on the part of Amgen, it is possible that it could still have been included owing to want of good faith on their part. In 1994, that appears to me to be a contention which should be rejected for the reasons already discussed in relation to error (b). The position as at 1984 with regard to error (b) and want of good faith is, I think less clear. However, even as at 1984, I consider that there was no want of good faith on the part of Amgen in relation to error (b). That is partly for the reasons discussed in relation to error (b) but also for some of the reasons for rejecting lack of good faith in relation to error (a). In relation to the latter aspect, I have in mind inherent improbability due to the risk of discovery, the uncertainty as to what happened in 1984, the fact that the error has to be assessed in the context of all the

other issues as at 1984 and the seriousness of the allegation. Accordingly, I am of the view that error (b) was not be attributable to want of good faith.

CONCLUSIONS

Amendment or revocation

167. Given that Amgen are seeking a deleting amendment of the Patent, namely a deletion of claims 19 to 25 inclusive, on the basis that the validity of the remaining claims is unaffected by any of the conclusions I reached in my earlier judgment, it appears to me, in light of my analysis of the earlier decisions, and in particular Gerber [1994] FSR 471, [1995] FSR 492, and Oxford Gene [2001] RPC 310 that the valid claims of the Patent are enforceable, and that I should give permission to amend as sought by Amgen.

168. However, in light of the arguments advanced on behalf of HMR with regard to amendment and revocation, and because the authorities do not speak entirely with one voice, it is appropriate to consider whether I would permit the amendment if I am wrong, and the issue is one of discretion. If the decision whether or not to grant permission to make a deleting amendment is a matter of discretion, but if, as Gerber [1994] FSR 471 and [1995] FSR 492 suggests, the valid claims of a partially valid patent are enforceable in any event, then it seems to me that the power to grant the amendment will, save in the most exceptional circumstances, always be exercised. There is simply no reason, whether from the view of the patentee or any potential infringer, to refuse the amendment, and there is a good reason to grant the amendment, namely to ensure that invalid claims do not remain on the record.

169. On the other hand, if HMR's primary position is correct, and there is not only a discretion whether or not to grant a deleting amendment, but, where the court refuses a deleting amendment, the patent must be revoked, there is no reason why the discretion should not be exercised on a more flexible basis. In the absence of the

conclusion being inconsistent with authority, I would have little hesitation on the facts of the present case in concluding that permission to amend should be granted to Amgen, assuming that the question of amendment is one of general discretion, and that, if amendment is refused, the patent will be revoked. My reasons for reaching that conclusion can be expressed fairly shortly. It appears to me that refusing the amendment, with the resultant revocation of the Patent, would be a wholly disproportionate penalty for Amgen, and would be a wholly disproportionate benefit for infringers and potential infringers, such as HMR. This is because:

- Only one of the three errors was attributable to want of reasonable skill or knowledge;
- None of the errors was attributable to want of good faith;
- The first error was due to an oversight or misunderstanding on the part of Amgen's US patent agent, the second error was only a mistake in light of my conclusion that certain urinary EPOs were extracted by workshop modifications of prior art, which was not a view shared by the European Patent Office, and the third error was that of someone to whom Amgen had reasonably entrusted some analytical work;
- The errors only impinged on six of the more than thirty Claims of the Patent;
- The errors were made in a patent which contained a very large amount of information and analysis, the rest of which has not been criticised;
- The errors do not appear to have misled anyone in a substantial way, save to the extent of HMR incurring substantial expense in relation to establishing their case on the issue, but that will be compensated in costs. In this connection, I appreciate that it cannot be established for certain that no one

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has suffered as a result of the errors, but no argument was advanced by HMR to suggest that that happened or unlikely to have happened.

170. On behalf of HMR, Mr Kitchin contends that I should nonetheless refuse permission to amend for three reasons. The first reason is the unsatisfactory way in which Amgen have conducted the present applications, and in particular the unsatisfactory and unreliable nature of the evidence given by Mr Borun and, to a lesser extent, Mr Odre. For the reasons already given, I accept that Mr Borun was indeed an unsatisfactory and unreliable witness, but he was not a dishonest witness; Mr Odre was not a wholly satisfactory witness, and was open to some criticism, in a way that Mr Brown (Amgen's European patent agent) and Dr Strickland were not. However, I cannot accept that, because a patentee's patent agent is an unsatisfactory witness, or even if he is a dishonest witness, that of itself should be enough to persuade the court to take a course which ultimately involves revoking the patent, in a case where the absence of the unsatisfactory or dishonest evidence of the patent agent, the court would not revoke the patent. This is not merely because the patentee cannot control the conduct of its patent agent in the witness box. It is more because, when giving evidence as to the drafting of the patent, the patent agent is not the agent of the patentee: he is a witness who is giving evidence about his conduct when he was an agent of the patentee. Accordingly, as a matter of principle, it seems to me that, unless it can be shown that the patentee contributed to or assisted in the unsatisfactory performance of the patent agent in the witness box, it would be inappropriate to hold the patentee liable in some way for that conduct. Quite apart from this, even if it is proper to take into account the criticisms that can fairly be made of Mr Borun (and, albeit to a much lesser extent, of Mr Odre) I do not accept that in the present case they would justify a revocation of the Patent if it is otherwise not justified, on the facts of the present case.

171. Secondly, HMR relies on the fact that Amgen wrongly persisted in seeking to justify the accuracy of error (a) at the trial in 2001. As to that, while I formed a firm view that error (a) was indeed an error, I do not think it would be right to penalise

Amgen, other than by making them pay the costs in relation to the issue, for maintaining that there was in fact no error. This is not least because, by the time of the hearing before me, the clear copy of a SDS-PAGE experiment, not previously available to Amgen and their advisers, had become available, and Professor Cummings had expressed the view, which he maintained on oath, that it showed COS rEPO demonstrating a slightly higher apparent molecular weight than Goldwasser uEPO. It is true that, I rejected that evidence, and that, while I acquitted him of dishonesty, I was critical of Professor Cummings, in that I thought that he behaved more as an advocate than as an expert witness. It is, I suppose, conceivable that he was encouraged, even strongly encouraged, by representatives of Amgen to give the evidence that he did, but there is no evidence to support that. It is therefore the case that a highly experienced and respected Professor, with substantial experience and reputation in the relevant field, was prepared to say on oath that what I have held to be an error was in fact accurate. In those circumstances, I do not think that this second point assists HMR's contention that, if I have a general discretion to refuse the amendment, I should exercise it.

172. HMR's third argument relies on the contention that Amgen have not satisfied the requirements which have been held on a number of occasions to be required to be satisfied before an amendment is granted. I refer, of course, to the five points identified by Aldous J in SmithKline at [1989] FSR 561 at 569, subsequently approved in Hsiung [1992] RPC 497 and Kimberley-Clark [2000] RPC 422. As I have said, while it would be presumptuous or worse for me not to consider those five points in the present case, I cannot accept that, unless an applicant for amendment has satisfied all of those requirements, then in any such case the court has to refuse the amendment.

173. In the present case, HMR's primary argument in relation to these five points is that Amgen have not been frank about the circumstances in which error (a) - and, to the extent that it can be relied on, error (b) – came into existence and came to be supported. In the sense that there has been no satisfactory explanation as to why Mr

Borun made the initial drafting mistake, and why nobody at Amgen spotted it, in 1984, and no explanation as to why the inconsistency of error (a) with the documentary evidence consisting of notebooks, papers, depositions and declarations, was not properly appreciated in 1994, that is a good point. Also, to the extent that I found the person who, if he had remembered, would have been in the best position to explain, namely Mr Borun, to be an unsatisfactory witness, that contention could also be said to be made out. However, I refer back to my conclusion that, as happens with many mistakes in many areas of life, there is no explanation, other than the fact that there must have been some misunderstanding or some oversight, or, if there was an explanation, the persons who could have explained it have either forgotten or could not be called to give evidence. In those circumstances, particularly in light of my finding of good faith, it seems to me it would be disproportionate to hold that Amgen should be penalised on this ground, particularly to the extent of depriving them of the Patent, which, on the hypothesis under which I am currently proceeding, is what would happen if I refuse leave to amend. In this connection, I should add that there can be no criticism of Amgen in failing to call Dr Lin or Dr Egrie: they are out of the jurisdiction, no longer employed by Amgen and have refused to come to give evidence despite Amgen's request.

174. Accordingly, whatever the proper approach to the question of amendment, I conclude that it would be right to permit Amgen to amend the Patent by deleting Claims 19 to 25 inclusive.

Damages, costs and expenses

175. If section 63(2) of the 1997 Act is to be construed as HMR contends, then a patentee will be deprived of the right to recover damages, costs and expenses (hereafter "Damages") if any part of the patent concerned can be shown to have been drafted without reasonable skill or knowledge. On that basis, as I have found that the inclusion of error (a) in the Patent, as originally granted by the European Patent Office, and as subsequently upheld by the Oppositions Division and the Appeal

Board, was due to want of reasonable skill and knowledge, it must follow that Amgen would not be entitled to Damages.

176. However, as stated earlier, it appears to me that the mere fact that there is one error in a specification, and that that error is attributable to want of reasonable skill and knowledge, does not necessarily mean that section 63(2) is automatically engaged. In my view, the court has to consider whether the specification was drafted with reasonable skill and knowledge, and the mere fact that one provision may not have been drafted to that standard does not of itself mean that the specification falls below that standard. Nonetheless, I would accept that, once it is satisfied that the drafting of a specific provision in the specification fell below the requisite standard, the court may take quite a lot of convincing before it concludes that the patentee has discharged the onus on it of establishing that the specification was nonetheless drafted with reasonable skill and knowledge.

177. There are undoubtedly a number of factors which can be cited to support the contention that the specification of the Patent was not drafted to the requisite standard. First, there is the fact that error (a) was not drafted with reasonable skill and knowledge in 1984. Secondly, there is my finding that Amgen and its agents also suffered from want of reasonable skill and knowledge when they maintained error (a) in the hearing before the Appeal Board in 1994, and indeed thereafter in the Opposition Division. Thirdly, the specification contained other mistakes, namely error (b) and error (c), which, while they were not attributable to want of reasonable skill and knowledge, were nonetheless mistakes related to error (a). Fourthly, error (a) was an important component in the Description which Amgen relied on when applying in 1984 for the claims which ultimately became Claims 19 to 25, and when seeking in 1994 to maintain those claims, which were themselves commercially important to Amgen. Fifthly, the very fact that the Patent was under consideration, albeit on a somewhat on and off basis, before the European Patent Office for 14 years can be said to make the want of reasonable skill and knowledge in connection with error (a) all the more marked.

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178. Over and above this, there is the fact that it is very much in the public interest that every part of a specification in a patent is carefully drafted, bearing in mind that patents are public documents with serious potential consequences for members of the public, including commercial competitors of the patentee. Furthermore, human nature is such that most errors in a specification will tend to favour the patentee. There is therefore obvious force in the point that, once a patent needs amendment because of an mistake which is attributable to lack of reasonable skill and knowledge, the court is scarcely doing its duty as envisaged by section 63(2) if it is too ready to hold that the existence of one or two errors attributable to want of reasonable skill and knowledge does not prevent the patentee avoiding the consequences of the section.

179. Against that, it seems to me that the court should equally not be too ready to find that every time that a patent needs amending because it has an error which is attributable to want of reasonable skill and knowledge, section 63(2) applies. To penalise a patentee every time there is such an error, which results in the need to amend the patent, appears to me not only to fly in the face of the actual words used by the legislature, but also to be likely to lead to the imposition of a disproportionate penalty in some cases.

180. Turning to the more specific points which favour the non-engagement of section 63(2) in the present case, it seems to me that they are as follows. First, the Patent is a very long and detailed document, in which only three errors have been identified, and only one of those errors is attributable to want of reasonable skill and knowledge. Secondly, HMR did not challenge the view expressed by Mr Bannerman, a patent agent of 30 years experience, and the current president of the General Legal Commission on Biotechnology Patents. Having read the Patent as granted originally by the European Patent Office and the Opposition Division, the decisions in 1994 and 1998 of the Appeal Board, and my judgment of 11th April 2001, he gave evidence as to various aspects relating to these applications, and concluded:

"[W]e have been looking in detail at one claim and one short passage in a long and complex specification. In my view, the skill in drafting overall was of the highest order and to end up with only the present areas of concern is to my mind, highly creditable."

181. No reason was advanced to challenge the impartiality of Mr Bannerman or the reasonableness of this conclusion; indeed, the conclusion was not challenged. Obviously, that does not bind the court, nor does it mean that it is not open to HMR to invite the court to take a different view. However, having considered the whole of the specification of the Patent in no little detail over a period of more than four weeks last year, and having considered parts of it in relation to the present applications, my view is that, taken as a whole, the specification was well and competently drafted.

182. Thirdly, if one focuses on error (a), it appears to me that, taken on its own, it did not have a particularly wide ranging effect. Whether one considers the claim which is now Claim 19 in the form and context of the specification as drafted in the original application, or as granted by the Examining and Opposition Divisions, or as proposed to be modified by the Appeal Board, it appears to me that it could and would have been granted in the same form as it was, and indeed would have been valid, if the only objection to the claim was the inaccuracy contained in error (a). That is because, on this hypothesis, while one would treat the contents of error (a) as notionally excised from Example 10, error (b) would remain, as would, at least until it was effectively withdrawn in 1994, error (c). So long as error (c) was present, there was a basis upon which Amgen could perfectly properly contend that recombinant EPO could be distinguished from prior art EPO on the grounds of carbohydrate content. Even after error (c), and with it the whole of the second paragraph of Example 10, had been excised from the Patent, it seems to me that error (b) would still have justified granting the claim which is now Claim 19, in its various forms. That is because error (b) appeared to establish that a particular recombinant EPO, namely CHO rEPO, had a higher apparent molecular weight by SDS-PAGE than the sole type

of urinary EPO which, at least in the opinion of the European Patent Office, represented prior art EPO, namely Goldwasser uEPO.

183. In my judgment, if Amgen had conceded that error (a) should be discharged because it was wrong, the Examining Division, the Opposition Division and the Appeal Board would each have nonetheless been prepared to grant the claim which has now become Claim 19 in the same form as they respectively thought was acceptable. This is because they would have concluded that, on the evidence available, at least one way of performing the invention claimed by the Patent produced a glycoprotein which could be distinguished on SDS-PAGE from the prior art. The only disadvantage to Amgen would have been that it would have been clear from their concession that, at least on the basis of their experiments, it would not have appeared that COS rEPO was within the ambit of the Claim. However, it is relevant in this connection to mention again that the commercially valuable process as described in the specification of the Patent involved manufacturing CHO rEPO, and not COS rEPO.

184. Fourthly, if error (a) had been the only error in the Patent, there would have been no need for Amgen to apply to amend the Patent. If error (b) had not been a mistake, I would simply have concluded that CHO rEPO, and any other recombinant EPO which fell within the ambit of the Patent, would fall within Claim 19, unless it had the same apparent molecular weight as, or a lower apparent molecular weight than, Goldwasser uEPO. Ironically, it is only because the Appeal Board took a different view from me on product-by-process claims, and I took a different view from the Appeal Board as to whether Lot 82 uEPO and Therapeutics uEPO constituted prior art, that Amgen need to amend the Patent and an argument can be run against them under section 63(2).

185. In this connection, however, the important point is that the reason I found Claim 19 invalid was not because of the mistake made in error (a), but because of the mistake which in my view underlies error (b). That mistake was that, at least in my

opinion, the apparent molecular weight by SDS-PAGE of urinary EPOs was variable to such a significant extent that, at least on the basis of the evidence as it seemed to me, it would be impossible to be confident whether a particular recombinant EPO did in fact have a higher apparent molecular weight than any prior art urinary EPO. One might test one's product against, say, six or seven different samples of urinary EPO, and find that it appeared to fall within Claim 19, but there would always be the possibility of there being another source of urinary EPO which manifested the same apparent molecular weight as one's product. That problem underlies error (b), but not error (a).

186. As I hope has been made clear, errors (b) and (c), although mistakes, are not attributable to any want of reasonable skill and knowledge on the part of Amgen. Error (b) is plainly based on a view which a reasonably skilled and knowledgeable person could take, and indeed mirrors the considered view taken by the European Patent Office in its letter from the Opposition to Amgen. Error (c) resulted from a mistake made by an expert in whom Amgen had reasonably placed reliance.

187. Fifthly, it does not seem to me that the Opponents before the Appeal Board, or indeed the Appeal Board, itself were relevantly misled. In their decision of 21st November 1994, the Appeal Board refer to the "consensus" among the Opponents that "the claims to the polypeptides lacked novelty" because "given an EPO preparation, it was impossible to establish whether it was uEPO or rEPO on the basis of the sugar composition". The Appeal Board then referred to the evidence of a number of different expert witnesses on behalf of the Opponents, including Dr Conradt. They went on to say that the contents of the first paragraph had "not been shown to be wrong" and stated "that recombinant EPO produced from COS-1 and CHO cell expression had a higher molecular weight than uEPO". The Appeal Board then said that Claim 19 in the form in which it had been originally accepted by the Examining Division and the Opponent Division "suggests merely that products different from uEPO can be obtained, not that there is any recognisable advantage in doing so".

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188. The Appeal Board then expressed the view that the evidence "reveals that... differences [between recombinant EPOs and urinary EPOs] can be attributed only to the particular cases under investigation and cannot be generalised to rEPO as a class". Consistently with this view, they went on to state that Amgen had been unable to show that any of the alleged "distinguishing features for rEPO is a "universal" one for the whole class of rEPO" and therefore these alleged differences between rEPO and uEPO, which included the molecular weight difference, were regarded by the Appeal Board "as not reliable". The Appeal Board expanded this view in these terms:

> "[T]here appears... to be no certainty of getting a particular rEPO glycosylation pattern. The glycosylation patent for uEPO would also appear to depend on the time of day, and physiological status of the patient from whom it is obtained. rEPO thus appears to share with uEPO the characteristic that the carbohydrate composition is to a considerable degree a matter of chance."

They also went on to make express reference to Amgen's submissions to the FDA.

189. I think that two points can fairly be made about these observations. First, it is clear that the Opponents were making the point that there was much evidence to suggest that many recombinant EPOs had the same apparent molecular weight as urinary EPO. That view is reinforced if one turns to the evidence of Dr Conradt to the Appeal Board. That evidence suggested in clear terms that Amgen's own experiments showed that COS rEPO had the same apparent molecular weight as prior art urinary EPO, and indeed Dr Conradt cited the published papers to which I have referred, as supporting that contention. Secondly, it does not appear that the Appeal Board was in any doubt as to the variability of the carbohydrate content, and hence the apparent molecular weight, of different types of recombinant EPO and urinary EPO, although of course they did not consider that the conclusions embodied in error (a) or error (b) were wrong.

190. In these circumstances, it is perhaps a little difficult to understand why the Appeal Board nonetheless allowed Claim 19 in the form proposed in Auxiliary Request 11. The Appeal Board expressed its reason shortly in these terms:

> "The basis for this restriction was simply given by reference to the first paragraph of Example 10."

As already mentioned, it seems to me that if error (a) had been excised from Example 10, but error (b) had remained, the Appeal Board would have had no good reason for reaching a different conclusion from that which they reached.

191. Bearing in mind these various factors, I have reached the conclusion that Amgen have established that the Patent was drafted with reasonable skill and knowledge. Although there was one error attributable lack of reasonable skill and knowledge, the specification as a whole was well drafted, and, taken on its own, the error concerned would not have led to the Patent being granted by the various sections of the European Patent Office (including the Appeal Board) in a form different from that which it was granted, and, indeed, it was not error (a), or the reason for my finding that it was a mistake, which resulted in my finding that Claim 19 was invalid.

CONCLUSION

192. I will therefore grant Amgen permission to delete Claims 19 to 25 (inclusive) from the Patent, and will declare that section 62(3), and indeed section 63(2), do not deprive Amgen from seeking damages, costs or expenses in relation to the Patent.

193. I should finally mention that the question of whether I should require a deletion from the first paragraph was touched on. Amgen were prepared to effect such a deletion, unless HMR then contended that the Patent should consequently be revoked on grounds of added matter. Mr Kitchin on behalf of HMR said nothing on this issue. On the evidence and arguments I have heard, there is plainly a case for saying that the

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reference to the performance of COS rEPO on SDS-PAGE should be removed. As at present advised, I see no need to delete the reference to CHO rEPO given that it did display an apparently higher molecular weight on SDS-PAGE than the only type of urinary EPO which, on the evidence I have heard, appears clearly to have been "pooled". As the questions of whether an amendment to the first paragraph ought to be made, the extent of any amendment, and the consequences of such an amendment, were not really explored in argument or evidence, I do not propose to deal with them, at any rate at this stage.