EXHIBIT 5
Part 1 of 2

Case No: HC 1999 Nos. 02916/02917
HC 1999 No. 03241

Neutral Citation Number: [2002] EWHC 471 (Patents)

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 21st March 2002

Before :

THE HONOURABLE MR JUSTICE NEUBERGER

Between :

HOECHST MARION ROUSSEL and others	**Claimants**
- and -	
KIRIN-AMGEN INC. and others	**Defendants**

Mr. David Kitchin QC and Mr. Richard Meade and Miss Lindsay Lane (instructed by **Messrs. Bird & Bird**) for the Claimants/Petitioners.

Mr. Antony Watson QC and Mr. Andrew Waugh QC and Mr. Tom Hinchliffe and Mr. Colin Birss (instructed by **Messrs. Taylor Joynson Garrett**) for the Defendants/Patentees.

Hearing dates : 4,5,6,7,8,19,20,21 February 2002

Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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Mr. Justice Neuberger

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Mr. Justice Neuberger:

INTRODUCTION

1. This is an application by Kirin-Amgen Inc. and others ("Amgen"):

   a. For the amendment of European Patent (UK) Number 148,605 ("the Patent") by deleting Claims 19 to 25 inclusive therefrom;

   b. For a determination that Amgen is entitled to recover damages, costs and expenses from Hoechst Marion Roussel Limited ("HMR") notwithstanding the amendment of the Patent.

   HMR oppose both parts of the application, and contend that the Patent should be revoked.

2. I have considered the Patent on a number of occasions, and in particular in a judgment given on 11th April 2001. In that judgment, I concluded that, subject to the question of amendment which now has to be considered, the Patent was valid, and that various parties, including HMR, infringed it.

3. The Patent relates to a protein called erythropoietin, or EPO for short, which is produced in healthy mammals in small, but vital, quantities. Its function is to stimulate the production of red blood cells which carry oxygen from the lungs to other parts of the body. The ability to synthesise EPO artificially has substantial commercial and therapeutic implications. Dr Fu-Kuen Lin, who was a member of a research team employed by Amgen, appears to have been the first person to have obtained the amino acid sequence of human EPO, and the DNA sequence of the human EPO gene. He also appears to have been the first person to have used human EPO DNA to enable artificial manufacture, or "expression", of EPO in certain types of cell, in particular the Chinese Hamster Ovary cell, or CHO cell, and the COS Monkey cell, or COS cell.

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4. Naturally occurring human EPO is only obtainable in minute quantities; it can be extracted from urine, and hence is known as urinary EPO, or uEPO. Artificially expressed EPO such as that obtained in accordance with the work of Dr Lin, is known as recombinant EPO, or rEPO. Human EPO is a glycoprotein, i.e. a protein (or polypeptide) with carbohydrate units, or residues, attached. It is during the process of being expressed in a mammalian cell (whether in a human cell naturally or artificially, or in a COS cell or CHO cell artificially) that human EPO becomes glycosylated – i.e. carbohydrate residues become attached to the polypeptide chain, or backbone.

5. Much of the technical background necessary to understand the issues in the main action (as discussed in the judgment of 11th April 2001 at paragraphs 41 to 131) is not germane to the more limited issues raised on these applications. However, one technique that should be mentioned is SDS-PAGE (discussed at paragraphs 122 to 131 of the earlier judgment). It is a method of assessing the relative molecular weights of different proteins, based on how far they migrate along a gel which is subject to an electric field. The further a protein proceeds along the gel in a particular time, the higher its apparent molecular weight. "Apparent", because it is a somewhat imprecise exercise, the mobility depending not only on weight, but also on the shape and electric charge of the protein.

6. The Patent as eventually granted contained a Description which ran to over 20 pages of closely printed material interspersed with another 20 pages of tables of polypeptide and DNA sequences. The Description included the following:

   a. An introduction which explained that the invention "relates generally to the manipulation of genetic materials and, more particular, to recombinant procedures making possible the production of polypeptides possessing part or all of the primary structural conformation [of EPO]";

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b. Over two pages describing "manipulation of genetic materials";

c. Over three pages explaining why EPO is "a polypeptide of interest";

d. A "brief summary" which effectively reproduced the claims, and then went on to explain how vertebrate cells, and in particular COS cells and CHO cells could be transfected with artificially made EPO DNA, which could then be used to express recombinant EPO;

e. A detailed description, which contained twelve Examples, effectively setting out the procedures involved in the claimed invention. In particular, Example 10 explained how CHO cells and COS cells could be transfected with the human EPO gene in a way which enables recombinant EPO to be expressed in substantial quantities.

7. There were 31 Claims in the Patent, as eventually granted. Claims 1 to 11 were to various DNA sequences. Claims 12 to 18 were to cells which had been transfected so as to be enabled to express EPO (and two of the Claims respectively referred to a transfected COS cell and a transfected CHO cell). Claims 19 to 26 were to various different types of recombinant polypeptide, i.e. to EPO which had been effectively manufactured substantially in accordance with the teaching of the Patent. Claims 20 to 25 were dependant on Claim 19. Claims 27 to 29 were process claims, and Claims 30 and 31 were claims to pharmaceutical composition substantially in accordance with the teaching of the Patent.

8. A more detailed description of the contents of the Patent is contained in paragraphs 132 to 183 of my earlier judgment.

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A GENERAL OVERVIEW OF THE FACTS

9. The first application for a United States Patent was made on behalf of Amgen on 13th December 1983, and the three other relevant subsequent applications were made on 21st February, 28th September, and 30th November 1984. (While not of central relevance to the present applications, Amgen made a fifth application on 23rd October 1987). Amgen's application for a European Patent was first filed on 12th December 1984, claiming a priority date by reference to the four earlier US applications. The US Patent applications, like the European Patent application were substantial documents, running to well over twenty thousand words, and including many tables (of amino acid sequences and DNA sequences), Examples, figures, and Claims.

10. As I have mentioned, Example 10 of the Patent was concerned with describing the artificial expression of human EPO in COS cells and in CHO cells which had been transfected with human EPO DNA constructed according to the teaching of the Patent. After the third US application had been made, three paragraphs were added to the end of Example 10 in the fourth US Patent application (made on 30th November 1984).

11. The three paragraphs (which I shall refer to as the first, second and third paragraphs respectively) at the end of Example 10 of the fourth US Patent application and of the European Patent application were in the following terms:

> "A preliminary attempt was made to characterise recombinant glycoprotein products from conditioned medium of COS-1 and CHO cell expression of the human EPO gene in comparison to human urinary EPO isolates using both Western blot analysis and SDS-PAGE. These studies indicated that the CHO-produced EPO material had a somewhat higher molecular weight than the COS-1 expression product which, in turn, was slightly larger than the pooled source human urinary extract. All products were somewhat heterogeneous. Neuraminidase enzyme treatment to remove sialic acid resulted in COS-1 and

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CHO recombinant products of approximately equal molecular weight which were both nonetheless larger than the resulting asialo human urinary extract. Endoglycosidase F enzyme (EC 3.2.1) treatment of the recombinant CHO product and the urinary extract product (to totally remove carbohydrate from both) resulted in substantially homogeneous products having essentially identical molecular weight characteristics" (emphasis added).

"Purified human urinary EPO and a recombinant, CHO cell-produced, EPO according to the invention were subjected to carbohydrate analysis according to the procedure of Ledeen, et al. *Methods in Enzymology*, 83(Part D), 139-191 (1982) as modified through use of the hydrolysis procedures of Nesser, et al., *Anal.Biochem.*, 142, 58-67 (1984). Experimentally determined carbohydrate constitution values (expressed as molar ratios of carbohydrate in the product) for the urinary isolate were as follows: Hexoses, 1.73; N-acetylglucosamine, 1; N-acetylneuraminic acid, 0.93; Fucose, 0; and N-acetylgalactosamine, 0. Corresponding values for the recombinant product (derived from CHO pDSVL-gHuEPO 3-day culture media at 100 nM MTX) were as follows: Hexoses, 15.09; N-acetylglucosamine, 1; N-acetylneuraminic acid, 0.998; Fucose, 0; and N-acetylgalactosamine, 0. These findings are consistent with the Western blot and SDS-PAGE analysis described above" (emphasis added).

"Glycoprotein products provided by the present invention are thus comprehensive of products having a primary structural conformation sufficiently duplicative of that of a naturally-occurring erythropoietin to allow possession of one or more of the biological properties thereof and having an average carbohydrate composition which differs from that of naturally-occurring erythropoietin."

12. Claim 40 included in each of the US Patent applications (which was effectively the predecessor of Claim 19 in the European Patent as eventually granted) was a claim to a recombinant glycoprotein product with the characteristics of human EPO. By the time of the fourth US Patent application, the description of the product was further

amended by adding the words "having an average carbohydrate composition which differs from that of naturally-occurring Human erythropoietin". That limitation to the Claim ultimately proved acceptable to the USPTO: it was included to enable the product claimed to achieve novelty over prior art. It was justified within the four corners of the Patent by the teaching contained in the first, second and third paragraphs of Example 10 ("the three paragraphs").

13. The European Patent application, which, as I have said, was first filed on 12th December 1984, was effectively in the same form as the fourth US Patent application. It included in Example 10 the three paragraphs, and included Claim 40 which was a claim to what, in summary terms, may be described as recombinant human EPO which differs from urinary EPO in its "average carbohydrate composition".

14. Meanwhile, Amgen was seeking the approval in the US from the Food and Drug Administration ("the FDA"), to enable recombinant EPO, manufactured substantially in accordance with the teaching of the Patent applications, to be marketed. An application to the FDA involves at least two stages. At the first stage, the applicant has to submit an Investigatory New Drug Application, known as an IND, and at the second stage it must submit a product license application, or PLA. In these documents, the applicant has to set out information relating to the drug which it wishes to market, to enable the FDA to be satisfied that it is safe and effective. In relation to recombinant EPO, Amgen submitted its IND on the 27th September 1985 and its PLA some time in October 1987.

15. Also in October 1987, Amgen started litigation in the United States against a Japanese company called Chugai, which was exporting artificial EPO from Japan into the United States. This litigation, "the Chugai litigation", lasted until 5th March 1991, when it culminated in success for Amgen. There was a further set of proceedings in the United States which started in about February 1990. These proceedings, "the interference proceedings", essentially involved a dispute, in the US Board of Patent Appeals and Interferences, as to whether Dr Lin or a Dr Fritsch had first made the

breakthrough which led to the claimed invention in the Patent. Dr Lin was backed by Amgen, and Dr Fritsch was backed by another commercial organisation called Genetics Institute ("GI"). The interference proceedings resulted in victory for Dr Lin and Amgen on 3rd December 1991.

16. During the late 1980s and early 1990s, the United States Patent and Trademark Office ("the USPTO"), was considering the various patent applications filed by Amgen in respect of recombinant EPO. This involved USPTO officials interviewing Amgen personnel, for instance on 30th July 1986, 20th July 1988, and 26th January and 24th May 1989. On at least one occasion, Mr Odre, Amgen's general counsel, and Mr Borun, Amgen's US patent attorney, attended. Following those interviews, Amgen formally responded to the USPTO's comments and requests on 5th June 1989. The USPTO initiated a so-called Office Action on 16th August 1994, which resulted in a response and a proposed preliminary amendment by Amgen during 1995. The process eventually culminated in the USPTO formally granting a patent to Amgen on 20th August 1996.

17. So far as the application for the European Patent was concerned, the Examining Division of the European Patent Office ("the Examining Division") informed Amgen's European Patent Agent, Mr Brown of Forrester & Boehmert, on 21st January 1988 that there would be a substantive examination, and that the characteristics of the product in Claim 40 (which was in the form which proved acceptable to the USPTO) were "inadequate and imprecise". Mr Brown and Mr Odre attended an informal interview on 2nd November 1988. Thereafter, on 21st April 1989, Amgen filed an amended description with the European Patent Office. On 15th June 1990, the Examining Division formally communicated to Amgen its decision to grant the Patent, and it was published formally on 25th July 1990. The Patent contained Claim 20 which was the predecessor of Claim 19 of the Patent in its ultimate form (and the successor to Claim 40 in the original application). As granted, this Claim was to a polypeptide of appropriate conformation and biological properties "characterised by being the product of procaryotic or eucaryotic expression of an

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exogenous DNA sequence". Those words were included to distinguish the claimed product from prior art uEPO. Example 10 of the Patent so granted contained the three paragraphs, although they did not, as I see it, need to be invoked to justify Claim 20 of the Patent as granted by the Examining Division.

18. Following the publication of the grant of the Patent by the European Patent Office, oppositions were filed on 24th and 25th April 1991. There were five Opponents, each of whom was a substantial commercial organisation, and one of whom was GI or an associate of GI. Amgen responded to these oppositions on 25th February 1992, and the Opponents replied during the latter half of 1992. The Opposition Division of the European Patent Office ("the Opposition Division") had a hearing on 25th and 26th November 1992, and gave its decision on 20th January 1993. In principle, the Opposition Division substantially found for Amgen. In so far as it required amendments to the Patent, none of them is relevant for the purpose of these applications. In particular, Claim 20, as accepted by the Examining Division, was also accepted by the Opposition Division. The Opponents appealed this decision, and each of them lodged their grounds towards the end of May 1993, and Amgen responded on 11th February 1994. After further written evidence and arguments had been filed with the European Patent Office, the provisional view of the Rapporteur was sent to the parties on 19th July and 25th August 1994. This resulted in a new Main Request from Amgen to the European Patent Office on 6th September 1994.

19. The Technical Board of Appeal of the European Patent Office ("the Appeal Board") then heard oral argument on the appeal between 20th and 23rd September 1994, and communicated its decision on 21st November 1994. During the hearing before the Appeal Board, Amgen conceded that the carbohydrate analysis of the recombinant EPO as contained in the penultimate sentence of the second paragraph could not be supported, in that it was clearly mistaken. In those circumstances, Amgen accepted that the second paragraph should be deleted from Example 10 of the Patent. There were arguments about the validity of some of the contents of the first paragraph, and

in particular the second sentence. There were also arguments about the validity of what was then Claim 20, the predecessor of the present Claim 19.

20. During the hearing of the appeal, it became clear to Amgen and their representatives that the Appeal Board was unlikely to be satisfied with the terms of Claim 20 (now Claim 19) as approved by the Opposition Division. Accordingly, in accordance with the normal practice before the Appeal Board, a number of auxiliary requests were made by Amgen during the hearing. These auxiliary requests involved suggested amendments to the claims of the Patent as granted in the Opposition Division. The procedure before the Appeal Board is such that a patentee is normally well advised to put forward as many auxiliary requests as are reasonably possible, because, unless one of them is accepted by the Appeal Board, the claim will be lost. In this case, so far as what is now Claim 19 is concerned, five different formulations were suggested by way of auxiliary request. That which found favour with the Appeal Board was the claim in Auxiliary Request 11, which was a claim to:

> "A recombinant polypeptide [having a similar structure to naturally occurring human EPO and with the biological properties of human EPO] and characterised by being the product of eucaryotic expression of an exogenous DNA sequence and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources."

This closing characterisation or limitation was dependent on the teaching of the three paragraphs in Example 10.

21. On 21st November 1994, the Appeal Board gave its decision, in which it indicated that the claim which is now Claim 19 was acceptable in the form suggested in Auxiliary Request 11. However, the Appeal Board referred the matter back to the Opposition Division, which entertained further written argument between Amgen and the Opponents as to the grant of the Patent. On 26th May 1997, the Opposition Division decided to affirm the grant of the Patent to Amgen, albeit with

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modifications, including the deletion of the second paragraph in Example 10 and an amendment to Claim 19 as approved by the Appeal Board (i.e. in accordance with Auxiliary Request 11). Claims 20 to 25 were claims to polypeptides and were contingent on the validity of Claim 19. That decision was again taken to the Appeal Board by the Opponents, but their appeal was effectively dismissed on 26th March 1998.

22. Accordingly, the Patent as finally granted by the European Patent Office:

a. Includes the first and third of the three paragraphs in Example 10;

b. Excludes from Example 10 the second of the three paragraphs;

c. Includes a claim, Claim 19, to "a recombinant polypeptide" which has appropriately defined sequences and biological properties "being the product of eucaryotic expression of an exogenous DNA sequence and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources";

d. Includes Claims 20 to 25 which are effectively contingent on Claim 19.

23. The validity of the Patent was challenged in this jurisdiction by HMR and a number of other parties, all of whom were alleged by Amgen to infringe the Patent. Following a five week trial, I concluded in my judgment of 11th April 2001 that the Patent was valid, subject to the proviso that I did not consider Claim 19 to be sufficient (which finding extended to Claims 20 to 25, given that they were contingent on Claim 19). I also held that HMR and various other parties infringed the Patent. My reasons for finding Claim 19 insufficient are in paragraphs 453 to 486 of the judgment of 11th April 2001. In essence, they were as follows. The apparent molecular weight by SDS-PAGE ("the apparent molecular weight") of urinary EPO could vary depending upon its source or sources. Recombinant EPO from transfected

CHO cells ("CHO rEPO") would have a higher apparent molecular weight than some urinary EPOs, and the same molecular weight as other urinary EPOs. In those circumstances, it appeared to me that it would be impossible for anyone who had obtained CHO rEPO according to the teaching of the Patent to be sure whether he had obtained a product which was within Claim 19. He might test its apparent molecular weight against that of urinary EPO from a number of different sources and find that it had a higher apparent molecular weight, but he could never be confident that there might not be a urinary EPO which had the same apparent molecular weight as its product. So far as recombinant EPO obtained according to the teaching of the Patent from COS cells ("COS rEPO") was concerned, I concluded that it had the same apparent molecular weight as, or a slightly lower apparent molecular weight than, urinary EPO, depending on the source of the latter.

24. Concurrently with this litigation, proceedings based on Amgen's US Patent were brought by Amgen against HMR and others in the United States. Those proceedings, "the US infringement proceedings", began in April 1997, and they resulted in success for Amgen, but HMR and others are currently appealing that decision. There have also been proceedings in Canada, South Africa and Australia, and, I believe, in other jurisdictions.

25. Amgen are appealing against my finding that Claim 19 is insufficient, and HMR is appealing against my finding that the Patent was otherwise valid, and also against my conclusion that it infringed the Patent. Without prejudice to their contention that Claim 19 is valid, Amgen are making what amounts to a contingent application to amend the Patent so as to delete Claim 19 (and the claims contingent thereon) and for a determination that, notwithstanding the need for this amendment, Amgen should nonetheless be entitled to recover damages, expenses and costs from HMR.

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THE PARTIES' CONTENTIONS

26. HMR contends that there were three errors in the Patent as granted to Amgen by the Opposition Division on 20th January 1993. Those errors are as follows:

a. The first paragraph of Example 10 described COS rEPO as having a "slightly larger" apparent molecular weight than urinary EPO, whereas there is not and never has been any evidence available to Amgen to support this;

b. The first paragraph of Example 10 described CHO rEPO (and indeed COS rEPO) as having a higher apparent molecular weight than urinary EPO, whereas Amgen knew that urinary EPO had a variable apparent molecular weight which was sometimes equal to that of CHO rEPO (and was sometimes equal to and sometimes greater than, that of COS rEPO);

c. The carbohydrate analysis of recombinant EPO as described in the second paragraph was demonstrably inaccurate.

I shall refer to these errors as error (a), error (b), and error (c) respectively.

27. HMR further contend that each of these errors demonstrates at least a want of skill and knowledge on the part of Amgen and its advisers in drafting the Patent. HMR go further than that, in relation to errors (a) and (b), arguing that there was a lack of good faith on the part of Amgen and their advisers in connection with those errors. It is said that Amgen and/or its agents effectively made up the information in error (a) in order to enable them to contend to the USPTO and to the European Patent Office that recombinant EPO was distinguishable as a product from naturally occurring urinary EPO, which was prior art. For essentially the same reason, HMR says, in relation to error (b), that Amgen withheld information in their possession which showed that, while CHO rEPO had a higher apparent molecular weight than some urinary EPOs, it

had the same apparent molecular weight as other urinary EPOs. HMR mounts no bad faith attack so far as error (c) is concerned.

28. HMR relies on the duty of an applicant for a patent, and indeed of a patent agent or patent attorney acting for such an applicant, to give proper disclosure to the European Patent Office. There is no dispute as to the nature or extent of the duty. Mr Borun described it as a "duty of candour", and I got the fairly firm impression that the duty on a patent attorney in the US is little different from that of a patent agent in the UK and Europe. Mr Brown, whose reliability is not challenged, said that a patent agent should not advance an argument or fact which he knew to be incorrect. However, he also said that he had a duty to his client to advance any reasonable argument which he could.

29. Amgen accept that error (c) was a mistake. Indeed, as I have mentioned, they accepted this in 1994 before the Appeal Board, as a result of which the second paragraph is now deleted from the Patent. Amgen also accept for the purpose of these applications, that, as a result of my judgment of 11th April 2001, errors (a) and (b) are indeed mistakes, albeit that they are appealing on both points. However, they deny that either error involved any lack of skill or knowledge on their part or on the part of their advisers, and, a fortiori, they deny any want of good faith.

30. Amgen contend that I should amend the Patent by deleting Claim 19, and any consequential claims. Indeed, Amgen argue that, even if I accept HMR's case on the errors, I should still grant them such relief. Amgen further say that there is no reason for disqualifying them from seeking damages for infringement and costs in the normal way against HMR, in light of my conclusion that HMR infringes Claims 1 and 26 of the Patent.

31. Particularly if I accept that there was any want of good faith on the part of Amgen or their advisers in drafting the Patent, HMR contends that it should not be amended, and that, in such circumstances, it should, indeed it must, be revoked. Even if I

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decide that the Patent should not be revoked, so that my finding of infringement against HMR stands (subject to it being reversed on appeal), HMR argues that it should not be liable for any costs, damages or expenses because of Amgen's want of good faith and/or want of skill or knowledge in drafting the Patent.

THE LAW

The Statutory framework

32. The Court has for a long time had the power to amend a patent which, in the absence of amendment, would be partially or wholly invalid. A patent is wholly invalid if all of its claims would be invalid in the absence of an amendment. A partially invalid patent is one which contains only some claims which are invalid, the rest being valid. The effect of refusing to amend a wholly invalid patent would self-evidently be that the patent would remain invalid, and accordingly it would have to be revoked. An amendment of a wholly invalid patent is therefore known as a validating amendment. However, where the Court refuses to amend a partially invalid patent, the position could be said to be more opaque. On the one hand, the invalid part might be said to infect the valid part, and the whole patent would therefore be invalid, and the patent would therefore be revoked in the same way as a wholly invalid patent. On the other hand, it could be that the valid claims should survive. In any event, if and when the Court decides to amend a partially valid patent, the amendment is known as a deleting amendment, because it involves striking out the invalid claims, but not making any amendment to the valid claims.

33. The current powers of the Court grant relief in respect of patents which were not wholly valid when granted is now governed by the provisions of the Patents Act 1977 ("the 1977 Act"), and all references hereafter to sections are to sections of the Act. The 1977 Act was passed, according to its long title, partly to give effect to the United Kingdom's obligations pursuant to certain conventions, among which is, of course, the European Patent Convention ("the EPC").

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34. Section 63 is concerned with the power of the Court to grant relief in respect of a partially valid patent. So far as relevant, it provides as follows:

> "(1) If the validity of a patent is put in issue in proceedings for infringement... and it is found that the patent is only partially valid, the Court... may, subject to sub-section (2) below, grant relief in respect of that part of the patent which is found to be valid and infringed.
>
> (2) Where in any such proceedings it is found that a patent is only partially valid, the Court... shall not grant relief by way of damages, costs or expenses, except where the plaintiff... proves that the specification for the patent was framed in good faith and with reasonable skill and knowledge, and in that event the Court... may grant relief in respect of that part of the patent which is valid and infringed, subject to the discretion of the Court... as to costs or expenses and as to the date from which damages should be reckoned."

35. Section 72 covers the power to revoke patents, and sub-sections (1) and (4) provide as follows, so far as relevant:

> "(1) Subject to the following provisions of this Act, the court... may on the application of any person... revoke a patent for an invention on (but only on) any of the following grounds, that is to say –
>
> ...
>
> (c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art;
>
> ...
>
> (4) An order under this section may be an order for the unconditional revocation of the patent or, where the court... determines that one of the grounds... has been established, but only so as to invalidate the patent to a limited

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extent, an order that the patent should be revoked unless within a specified time the specification is amended under section 75..."

36. Section 75(1) deals with the power to amend patents and it is in these terms:

> "In any proceedings... in which the validity of the patent is put in issue the Court... may, subject to section 76 below, allow the proprietor of the patent to amend the specification of the patent in such manner, and subject to such terms as to advertising the proposed amendment and as to costs, expenses or otherwise, as the Court... thinks fit."

37. Article 138 of the EPC is concerned with revocation of a European patent. Article 138(1) sets out the grounds upon which a European patent can be revoked, and they are mirrored in section 72(1). Article 138(2) is in these terms:

> "If the grounds for revocation only affect the European patent in part, revocation shall be pronounced in the form of a corresponding limitation of the said patent. If the national law so allows, the limitation may be effected in the form of an amendment to the claims, the description or the drawings."

38. Although the 1977 Act as expressed in its long title to be intended to give effect to certain international conventions, section 130(7) sets out those sections of the 1977 Act which are expressly intended to give effect to the obligations of the United Kingdom under the EPC. None of the sections to which I have referred are included.

The Issues

39. The nature of the amendment sought by Amgen in the present case is a deleting amendment, because I held that Claims 19 to 25 were invalid, and that the remaining Claims of the Patent were valid. Amgen contend that, in these circumstances, I should grant the amendment because the Claims other than Claims 19 to 25 ("the

valid Claims") will be valid and enforceable whether I grant the amendment to delete Claims 19 to 25 ("the invalid Claims") or not. However, HMR argues that, unless I grant permission to amend by deleting the invalid claims, the presence of the invalid Claims will infect the whole Patent, and it will have to be wholly revoked.

40. If Amgen are correct, and the valid claims of the Patent would be enforceable whether or not the invalid claims are deleted, it seems to me virtually inevitable that I should grant the amendment to delete the invalid claims. It would prejudice nobody, including any infringer of the valid claims, if I delete the invalid claims in those circumstances, and it would be nothing but a nuisance or worse if the invalid claims remained on the register. On the other hand, if HMR is correct, and refusal to delete the invalid Claims means that the Patent must be revoked, then the questions of revocation and amendment are so closely connected as to be different sides of the same coin.

41. If HMR's contention on this point of principle is correct, Amgen say that, however strong HMR's case is in respect of the errors in the drafting of the Patent, it would represent a disproportionate penalty for Amgen if the court refused the amendment. However, relying on what it says is Amgen's lack of good faith and/or lack of skill and knowledge, but also on Amgen's conduct, HMR contends that I should refuse the amendment sought by Amgen and revoke the Patent. That raises the question of the proper approach to the discretion of the court to revocation and amendment, if HMR's case on the proper approach in principle is correct.

42. Assuming that the Patent is not revoked, it is then necessary to consider the proper approach to the granting of relief in light of the provisions of section 63. The parties are agreed that, if section 63(2) does not apply, then the court may (but need not) grant relief in favour of the patentee against an infringer. There was little discussion as to the circumstances in which the court might refuse relief to the patentee if section 63(2) does not apply.

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43. The parties are also agreed that if section 63(2) applies, i.e. if I am satisfied that the specification of the Patent was not drafted in good faith or with proper skill and knowledge, then the court has no alternative but to refuse relief by way of damages, costs or expenses. The more difficult question is the proper approach to the question of whether the specification was drafted in good faith and with reasonable skill and knowledge.

44. In this connection, HMR's case is that if the court is satisfied that any part of the specification whatever has not been drafted in good faith or with reasonable skill and knowledge, then it is bound to conclude that the specification has not been drafted to the requisite standard, because the reference to "the specification" in section 63(2) must be taken as a reference to each and every part of the specification. On the other hand, Amgen's contention is that the mere fact that one or more parts of the specification can be shown not to have been drafted to the requisite standard does not of itself bring section 63(2) into play automatically. They argue that the court has to ask itself, bearing in mind the findings it has made about the defective parts of the specification, whether, viewed as a whole, the specification has been drafted to the requisite standard.

45. I propose to deal with these questions in turn, albeit that at least some of them clearly cannot be disposed of purely by reference to abstract principle. The answer must depend, at least in part, on the contents of the particular patent and the facts of the particular case.

Partially valid patents: introduction

46. Amgen's contention, as advanced by Mr Andrew Waugh QC (who appears with Mr Antony Watson QC, Mr Tom Hinchliffe and Mr Colin Birss) is essentially double-barrelled. First, a partially valid patent is valid and enforceable, even without the grant of a deleting amendment (i.e. the deletion of the invalid claims), and therefore there is simply no reason for refusing to grant the deleting amendment. Secondly, the

court should strive to construe the 1977 Act so as to comply with the mandatory terms of the first sentence of Article 138(2), which, in the case of a partially valid patent, requires the court to fashion a remedy which effectively retains the valid part of the Patent. HMR, on the other hand, contends that the provisions of the 1977 Act make it clear that the court retains a discretion whether or not to amend a partially valid patent, and that, if it declines to do so, the whole patent must be revoked.

47. If the matter were free of authority, then, in light of the provisions I have cited from the 1977 Act and of the EPC, I would have concluded this issue in favour of Amgen. First, while I accept that the relevant sections of the 1977 Act for this purpose are not included in section 130(7) as having been expressly enacted to ensure compliance with the EPC, it appears to me that one should construe the provisions of the 1977 Act, in so far as it is properly possible to do so, so as to arrive at a result which is consistent with the United Kingdom's international obligations. In that connection, it appears to me that the first sentence of Article 138(2) of the EPC is intended to be mandatory: not only is that indicated by the words "shall be", but it is also supported by the contrast with the qualifying nature of the words which govern the second sentence of Article 138(2).

48. Secondly, while the words of section 75(1) appear to give the court a discretion whether to permit an amendment, and that discretion applies to deleting amendments as well as validating amendments, the way in which section 63(1) is expressed strongly suggests that, if the invalidity only affects some of the claims of a patent, the remaining claims nonetheless remain valid. If, in the absence of a deleting amendment, a partially valid patent would have to be revoked, then section 63(1) would have to be treated as subject to an implied qualification, namely that it only applies where the court has exercised its discretion to grant the deleting amendment necessary to remove the invalid claims. The court is slow to imply terms into Statutory provisions.

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49. The argument the other way, advanced by Mr David Kitchin QC (who appears for HMR with Mr Richard Meade and Ms Lindsay Lane) essentially rests on section 72(4). This appears to apply to both partially and wholly invalid patents, and the second part of the sub-section suggests that if either type of patent is not amended to cure the invalidity, the patent as a whole should be revoked. I am of the view that, notwithstanding its undoubted force, this point should be rejected. It is true that sub-sections (1) and (4) of section 72 are expressed in discretionary terms: in each case, the court "may" make the revoking order. However, that discretionary power must be construed in the context of the 1977 Act as a whole, and, I would have thought, taking into account the provisions of the EPC. In practice, the way in which the discretion should be exercised is normally pretty clear. Thus, if any of the grounds established in section 72(1) apply to all the claims of a patent and an amendment is not granted, then it is hard to conceive of circumstances where the court would do other than revoke the patent, despite the word "may" in the sub-section. It does not therefore seem to me to be difficult to conclude that, where only some the claims of a patent have been held to be invalid under section 72(1), then, in light of section 63(1) and Article 138(2), the court should, at least in the absence of the most exceptional circumstances, grant a deleting amendment, and thus uphold the patent as amended.

50. Quite apart from this, I consider that section 72(4) is not inconsistent with Amgen's case. All that it does in relation to an invalid patent is to provide that, if it is not amended within a specified time, then it is revoked: it says nothing about the circumstances in which the court should or should not grant an amendment. In other words, the purpose of section 72(4) in relation to a partially valid patent, could be said to be to ensure that the patentee amends it promptly, so that invalid claims do not remain on the record. Thus, section 72(4) is not concerned with how the court exercises its power in relation to granting or refusing amendments (whether deleting or validating), but with what happens if the patent is not amended. It therefore does not impinge on the issue of whether or how the court should exercise its power to grant deleting amendments, or indeed validating amendments.

51. At first sight, it may be thought to be desirable that, in order to encourage patentees and their advisers to be honest and careful in drafting patents, the court should retain the right to refuse even a deleting amendment, and in those circumstances to revoke the patent. However, I think the answer to that point is to be found in section 63(2). The effect of that section is that, if the court concludes that the patent has not been drafted with the requisite degree of honesty, skill and knowledge, then, even if the patent survives as amended, the patentee is debarred from recovering any compensation or costs in relation to infringement. That should not discourage the patentee from applying to amend: if the court concludes that the patent is only partially valid, it can require a deleting amendment, which must be pursued by the patentee, failing which there is the sanction of revocation in section 72(4).

52. As I see it, section 63(2) is wide in its effect. Even if inaccuracies in the patent do not in fact bear on a particular infringement and have not in any way misled or impinged on a particular infringer, the patentee will nonetheless be unable to recover any damages, costs or expenses in respect of the infringement from such an infringer, unless he can establish that the specification was indeed drafted in good faith and with reasonable skill and knowledge. Accordingly, it seems to me that, by enacting section 63(2), the legislature has effectively imposed a wide ranging and substantial sanction against a patentee whose patent has not been drafted to an acceptable standard.

Partially valid patents: the cases before 1999

53. I turn to consider the effect of the authorities on this issue. There is no doubt that the courts have for a long time recognised the difference between a deleting amendment and a validating amendment: the distinction was discussed more than 35 years ago in C. Van der Lely NV –v- Bamfords Limited [1964] RPC 54. In that case, which was concerned with earlier legislation, the Patents Act 1949, the Court of Appeal expressed some uncertainty as to the consequences to the patent of refusing a deleting amendment. However, more recent authority suggests that the valid claims in a

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partially invalid patent are enforceable even in the absence of an amendment deleting the valid part.

54. In Gerber Garment Technology Inc. –v- Lectra Systems Limited [1994] FSR 471 at 483, Aldous J said this:

> "If it was the law in 1919 that a patent with an invalid claim was invalid until amended, then it is no longer the law. The Court has power to grant relief in respect of a partially valid patent without requiring amendment."

He reached that decision based on his earlier decision in Hallen Co. –v- Brabantia (UK) Limited [1990] FSR 134 at 138, and on the reasoning of the Court of Appeal in C. Van der Lely [1964] RPC 54.

55. The same view was taken by Millett LJ when Gerber went to the Court of Appeal. At [1995] FSR 492 at 499, he said:

> "[S]ection 63... has swept away the old rule that the presence of an invalid claim rendered the whole patent invalid. Instead, such a patent is now treated as "partially valid", and provided that the specification for the patent was framed in good faith and with reasonable skill and knowledge, the Court *may* grant relief in respect of the valid claims found to have been infringed."

56. More recently, in the Court of Appeal, Aldous LJ in Lubrizol Corp –v- Esso Petroleum Limited [1998] RPC 727 at 790 in a passage at lines 6 to 17 referred to cases where "a Court has held that a patent is partially invalid and partially valid". He continued:

> "In such a case it can grant relief without requiring amendment or may direct that it be amended to its satisfaction. Thus, if a claim specifies more than one

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invention, it may grant relief in respect of one of those inventions even though the other invention is invalid."

57. These observations therefore suggest that, in the case of a partially valid patent, the valid claims are enforceable even in the absence of a deleting amendment, i.e. an amendment deleting the invalid claims. If that is right, then it seems to me that it would be little short of absurd to refuse a deleting amendment, save (perhaps) in the most exceptional circumstances. In any particular case, the patentee and any alleged infringer of the valid claims are in no better and no worse position whether the deleting amendment is granted or not, and the public is clearly better off with the deleting amendment, because it is more desirable that invalid claims should not remain on the record. It also appears to me that, if the claims of a partially valid patent are enforceable and valid even in the absence of a deletion, it would be inconsistent to conclude that the refusal of an amendment to delete the invalid claims would lead to revocation of the patent. If that were the law, then no proprietor of a partially valid patent would apply for a deleting amendment, if he was in his right mind. Quite apart from anything else, that would scarcely be in the public interest, although, as mentioned above, the court, of its own motion, can require the patentee to amend.

58. There is one case which can be said to suggest that, even in the case of a partially valid patent, a refusal by the court to grant a deleting amendment will lead to revocation. I have in mind what was said by Aldous J in Chiron Corporation –v- Organon Teknika Ltd (No. 7) [1994] FSR 458 at 460:

"The defendants submitted that this is a case where the Court should not exercise its discretion so as to allow the amendment. Counsel did not shrink from the conclusion that he said resulted, namely that the patent should be revoked, thereby depriving the plaintiffs of any patent protection for the invention that I held had been made."

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59. That passage appears merely to record as submission what was said in the second sentence, without actually accepting its correctness. However, what Aldous J said immediately after that passage provides a degree of support for the view that he accepted the submission; he said:

> "Clearly such a finding would be harsh and would only seem to provide justice if there are very exceptional circumstances."

Further, in a subsequent passage in the judgment at [1994] FSR 463 Aldous J said this:

> "In cases of deletion, a patentee will not be deprived of the fruits of his invention unless there are very compelling reasons to do so."

60. However, it may well be that the contrary view was not argued, or that Aldous J was content to proceed on the assumption that the submission was correct, on the basis that it was a favourable assumption to the Opponents (whose case he ultimately rejected) because, if the valid parts of the patent had been enforceable even if the invalid parts had not been deleted, there would simply have been no reason not to delete the invalid parts.

61. Before turning to recent authority, it appears to me that the balance of the authorities so far considered plainly favours the conclusion that the valid claims of a partially invalid patent are enforceable irrespective of whether or not the patent is amended. From that, at least as I see it, it should follow that, save in perhaps the most exceptional circumstances, the court should grant a deleting amendment virtually as a matter of course, once it has held that certain claims of the patent are valid. However, this conclusion has to be judged in light of more recent authority.

Partially valid patents: the law since 1999

62. Kimberley-Clark Worldwide Inc. –v- Procter & Gamble Limited [2000] RPC 422 was relied on by HMR. It was a case concerned with a validating amendment. Laddie J held that, contrary to previous practice, the court should, almost as a matter of course, grant a validating amendment, in light of the practice of the European Patent Office in relation to European patents generally. The Court of Appeal disagreed. In his judgment, Aldous LJ referred to his judgment at first instance in SmithKline & French Laboratories Limited –v- Evans Medical Limited [1989] FSR 561 at 569, where he had said this:

> "The discretion as to whether or not to allow amendment is a wide one and the cases illustrate some principles which are applicable to the present case. First, the onus to establish that amendment should be allowed is upon the patentee and full disclosure must be made of all relevant matters. If there is a failure to disclose all the relevant matters, amendment will be refused. Secondly, amendment will be allowed provided the amendments are permitted under the Act and no circumstances arise which would lead the court to refuse the amendment. Thirdly, it is in the public interest that amendment is sought promptly. Thus, in cases where a patentee delays for an unreasonable period before seeking amendment, it will not be allowed unless the patentee shows reasonable grounds for his delay. Such includes cases where a patentee believed that amendment was not necessary and had reasonable grounds for that belief. Fourthly, a patentee who seeks to obtain an unfair advantage from a patent, which he knows or should have known should be amended, will not be allowed to amend. Such a case is where a patentee threatens an infringer with his unamended patent after he knows or should have known of the need to amend. Fifthly, the court is concerned with the conduct of the patentee and not with the merit of the invention."

As he pointed out, that passage was accepted by the Court of Appeal in Hsiungs' Patent [1992] RPC 497.

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63. There is no doubt in my mind that, so far as validating amendments are concerned, the reasoning and decision in Kimberley-Clark [2000] RPC 422 establishes that the 1977 Act gives the court a genuine discretion whether or not to grant such amendments, and its effect is that, if it refuses to do so, then the court should revoke the patent. It also appears to me that there is force in the point that the reasoning of Aldous LJ in Kimberley Clark [2000] RPC 422 is to the effect that the existence of the discretion whether or not to grant permission to amend, and the general approach to such discretion, applies equally to deleting amendments. However, any observations that the Court of Appeal in a case relating to validating amendments, even from a source as authoritative as Aldous LJ, have to be read in the context of the particular case. In addition, one must of course distinguish between those parts of his reasoning which are plainly ratio decidendi and those which are strictly obiter. If, as I believe to be the case, there are good grounds, in light of principle, authority (going back to Van der Lely in 1964), Statute (section 63), and Treaty obligations (the EPC), to distinguish between validating amendments and deleting amendments, then it seems to me that a decision and reasoning of the Court of Appeal in relation to a case involving validating amendments can properly be treated, where appropriate, as strictly obiter so far as deleting amendments are concerned. I express that view in a qualified way, because, in so far as the reasoning in the Court of Appeal in relation to validating amendments clearly applies equally to deleting amendments, it would not be right for me to depart from it. However, in my judgment, there is nothing in the reasoning in Kimberley Clark [2000] RPC 422 which requires me to depart from the conclusion I have reached on the basis of the Statutory and EPC material and the earlier cases. I reach that conclusion not only on the basis of consideration of the judgment in Kimberley Clark [2000] RPC 422 itself, but also, indeed more, on the basis of subsequent authority.

64. While there are passages in the judgment of the Court of Appeal in Kimberley Clark [2000] RPC 422, which may indicate that the court has a discretion whether or not to grant deleting amendments as well as validating amendments, the point seems to me

to have been more specifically focussed on in Oxford Gene Technology Limited –v- Affymetrix Inc. (No. 2) [2001] RPC 310. That was another decision of the Court of Appeal concerned with validating amendments rather than deleting amendments. In his judgment, Aldous LJ said at [2001] RPC 320 that "Article 138(2) essentially corresponds to section 63(1) of the 1977 Act...". He then turned to the argument that "to give effect to Article 138(2), the court has to exercise its jurisdiction under section 75 so as to permit the amendments, if they would have the result that [the] patent would be valid". That argument was rejected in that case (which related to validating amendments) on the basis that:

> "Section 63 is concerned with a case where the patent is partly valid as is Article 138(2); whereas section 75 permits amendment to validate an invalid patent. That difference was exposed in Van der Lely N.V. –v- Banfords Limited [1964] RPC 54" (paragraph 36).

65. Later on the same page, [2001] RPC 321, and, to my mind crucially for the purpose of the issue before me, Aldous LJ continued in these terms at paragraph 39:

> "We did not hear argument on the amendments sought by OGT, but on their face they appear to be of the kind designed to validate an invalid patent rather than to limit the patent to a part which is valid. Thus it would seem that the court would have to exercise its discretion under section 75 when considering the amendments. If the amendments had been of the kind which reflected the fact that one claim was valid, then section 63 could apply provided that the claim was infringed. In those circumstances the word "may" in section 63 might be construed in a permissive sense to give effect to the word "shall" in Article 138(2)."

The contention that the Court of Appeal took the view that, by enacting section 63, the legislature gave effect to the first sentence of Article 138(2) is reinforced by the

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apparent equating of the two provisions in paragraph 41 of the judgment at [2001] RPC 322.

66. Unlike Oxford Gene [2001] RPC 310, and indeed unlike Kimberley Clark [2000] RPC 422, the present case is indeed of a kind which falls within the penultimate sentence of the passage I have quoted from in paragraph 39 of Aldous LJ's judgment in Oxford Gene at [2001] RPC 321. It appears to me that, in those circumstances, the last sentence of that passage suggests, to put it at its lowest, that it might well be the case (i.e. that there is no authority which precludes the conclusion) that, in order to give effect to the first sentence of Article 138(2), the court should grant an amendment, because it is a deleting amendment and there are valid claims.

Partially valid patents: conclusion

67. Accordingly, I conclude that where an amendment is solely a deleting amendment, it should, save (possibly) in an exceptional case, be granted. It seems to me that that conclusion is (a) consistent with the United Kingdom's Treaty obligations under Article 138(2), (b) consistent with the natural meaning and effect of section 63(1), (c) not inconsistent with the provisions of section 72 and section 75, (d) consistent with the well accepted distinction between deleting and validating amendments which goes back to Van der Lely [1964] RPC 54, (e) logically and commercially sensible in light of the law as laid down in Gerber [1994] FSR 471 and [1995] FSR 492, and (f) open to me in light of Oxford Gene [2001] RPC 310. Accordingly, I conclude that, where the amendment sought to be made to a patent is purely a deleting amendment, because there are claims which would be valid even in the absence of the invalidity which has been established and in the absence of the deletion, the court should grant the deleting amendment.

Discretion to allow or refuse amendment

68. Assuming (contrary to my view) that there is a power to refuse a deleting amendment, then it appears to me that the cases support the proposition that the court should be very slow to refuse a deleting amendment.

69. In this connection, I have already quoted the observations of Aldous J in Chiron (No. 7) at [1994] FSR 460. That approach seems to me to have been followed in subsequent cases. Thus, in Mabuchi Motor KK's Patents [1996] RPC 387, Jacob J permitted an amendment involving the deletion of claims even though he had "no doubt that the patent was not framed with reasonable skill and knowledge" (see at [1996] RPC 402 lines 44 and 45) and even though he thought that the inventor in that case "never thought his invention was wider than that which is now claimed" (see at [1996] RPC 403 lines 11 to 12). The same view was taken by Pumfrey J in Nutrinova Nutrition Specialities & Food Ingredients Gmbh –v- Scanchem UK Limited (No. 2) [2001] FSR 831 at 837 when he referred to the need for "exceptional circumstances" before the Court would refuse permission to amend by way of deletion.

70. HMR contends that, even where a deleting amendment of a patent is sought, the five factors enunciated by Aldous in SmithKline at [1989] FSR 569, as subsequently approved by the Court of Appeal, and as quoted above, must be applied. In this connection, I should add that in Kimberley-Clark at [2000] RPC 422 at 438, Aldous LJ emphasised that the obligation to disclose "has been curtailed with the advent of active management of cases by the judges". In Oxford Gene [2001] RPC 310 at 317, Aldous LJ stated that, while "the obligation of good faith requires the patentee to put forward correct reasons for the amendment", there is "no obligation upon a patentee... to waive privilege in respect of any document" and that "the maintenance of privilege does not enable the Court to draw an adverse inference against the person who maintains his privilege".

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71. HMR contends that, on the basis that amendment is a matter of discretion, the five factors, now that they have been approved twice by the Court of Appeal, should be applied in a deleting amendment case. The five factors having not only been laid down and applied by this Court, but also approved by the Court of Appeal, have to be accorded great weight. However, I am reluctant to conclude, even in light of their impeccable pedigree, that they should be applied mechanically, at any rate in a case such as the present. First, assuming in HMR's favour, that the power to grant an amendment is a matter of discretion, because of the word "may" in section 75(1) of the 1977 Act, then it seems to me inappropriate to treat that discretion as fettered by judge-made rules, although, of course, any rules which have been applied in this Court and approved by the Court of Appeal must at the very least be considered, and, indeed, must provide useful guidance. In this connection, the imposition of judge-made rules on the exercise of a Statutory or quasi-Statutory discretion was recently disapproved by the Court of Appeal in Denyse Audergon –v- La Baguette Ltd (23rd January 2002, Times Law Report of 31st January 2002).

72. Secondly, if, as the authorities indicate, the discretion should almost always be exercised in favour of granting a deleting amendment, then that first point is reinforced in this case. Thirdly, the extent to which the five factors are to be applied must depend upon the sort of considerations identified by Aldous LJ, namely active case management and maintenance of privilege. Fourthly, at least in my view, it must be inevitable that guidelines of this sort have to be applied with a degree of flexibility. For example, there may be a case where a patentee, who satisfies the other requirements, has failed to apply to amend within a reasonable time, but that this has caused no prejudice to anyone, or such prejudice that it has caused can easily be remedied by ordering the patentee to pay a relatively small amount of money. If refusal of the amendment would lead to a very valuable patent being revoked, then, at least in some circumstances, it would seem quite disproportionate that a patentee who had delayed unreasonably, possibly for a relatively short time, should be refused an amendment and therefore deprived of his patent, even though there was no other reason to criticise the patentee in relation to the amendment or otherwise.

73. That is not intended to detract from the salutary guidelines laid down by Aldous J in SmithKline at [1989] FSR 561 at 569. In relation to delay, for instance, even if my view is correct, a patentee who is aware that his patent requires amendment should not assume that (if the grant of an amendment is indeed a discretionary matter) the amendment will automatically be granted if the only criticism of his conduct is unreasonable delay. Each case will have to be judged on its own particular facts, and any patentee who delays does so at his own risk. Furthermore, even if the court concludes that it should grant the amendment (either as a matter of pure discretion or because its discretion is effectively trammelled) there appears to me to be no reason why permission to amend should not be subject to conditions in an appropriate case, and obviously where the patentee's conduct is worthy of criticism, the court may feel that the criticism should be reflected in conditions.

Damages, expenses and costs: if section 63(2) does not apply

74. Section 63(1) gives the Court a discretion to grant relief against an infringer in a case where the patent is amended. However, where the patentee fails to establish that "the specification for the patent was framed in good faith and with reasonable skill and knowledge", section 63(2) effectively prohibits the Court from granting relief "by way of damages, costs or expenses", but there is nothing to take away the Court's discretionary power to grant other relief (e.g. injunctive relief).

75. In my view, although the power to grant relief against an infringer of a valid claim in a patent which includes invalid claims is discretionary (assuming that the patent was framed in good faith and with reasonable skill and knowledge), the Court would normally grant such relief against an infringer in such a case unless satisfied that the infringer was in some way unfairly misled by the invalid claims of the patent. Further, it seems to me that the mere fact that a patent may have been drafted so as to include invalid claims should not, in the absence of special factors, prevent the

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patentee being entitled to the full range of relief against an infringer of one or more of the valid claims, provided it is a case where section 63(2) does not apply.

76. The view that the Court will normally accord relief under section 63(1) is supported by observations, at first instance and in the Court of Appeal. Thus, there is a statement by Aldous J in Hallen at [1990] FSR 134 at 149 to this effect:

> "[It] is for a defendant to establish that special conditions exist before terms will be imposed or a patentee will be deprived of part of his damages. A patentee who has made an invention, disclosed it to the public in his specification and established that his specification was framed in good faith and with reasonable skill and knowledge is entitled to the full rewards provided by the law unless some special circumstances exist."

77. Further, in Gerber at [1995] FSR 492 at 499, Millett LJ said, in relation to a case where the patent contained invalid claims as well as valid claims, and where the defendant had infringed a valid claim:

> "[I]t will remain the fact that the defendant has infringed a valid claim, and that the plaintiff ought not to be deprived of his right to damages in respect thereof without good reason. If the presence of the invalid claims has induced the defendant to act as he did, then it would be unjust to order him to pay damages prior to the date on which the invalidity of the claims was established. If, on the other hand, the presence of the invalid claims has had no effect upon the defendants' conduct, then ordinarily it would not be just to deprive the plaintiff of any part of his damages."

Damages, costs and expenses: section 63(2)

78. As I have said, section 63(2) appears to be mandatory in its effect. It imposes the burden on a patentee, whose patent the court has found to be partially invalid, to

establish that the patent was drafted in good faith and with reasonable skill and knowledge. If he does not do this, then, even if his patent remains (at least partially) valid (either because it is amended or because it does not need amendment) he cannot claim damages costs or expenses from an infringer. In this connection, the law was helpfully summarised by Aldous J in Chiron (No. 7) [1994] FSR 458 at 467 to 468. Quoting from his earlier decision at first instance in Hallen at [1990] FSR134 at 142, he said this:

> "[I]t is my view that section 63(2) imposes upon a plaintiff a duty to prove on the balance of probabilities two things: first that the specification was framed in good faith. That requires a plaintiff to prove that the specification was framed honestly with a view to obtaining a monopoly to which, on the material known to him, he believed he was entitled. Secondly, that the specification was framed with reasonable skill and knowledge. The words "skill and knowledge" are a composite phrase relating to the competence employed in framing the specification and require the specification as framed to be in the form in which a person, with reasonable skill in drafting patent specifications and a knowledge of the law and practice relating thereto, would produce."

79. Aldous J went on to explain that, in making those observations:

> "I did not have in mind the possibility that the draftsman may not have been properly instructed on the details of the invention. In such a case, a patentee cannot be in a better position than the patentee who properly instructs the draftsman."

80. A question which does not seem to have been considered in any of the cases to which I have been referred, is the tension between the inevitable concentration of the parties and the Court on the skill and knowledge involved in the drafting of a specific passage in the patent, and the skill and knowledge employed in the drafting of the patent as a whole. In this case, as in I suspect virtually every case involving a dispute

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as to the applicability of section 63(2), the evidence and argument have focused on the drafting of specific passages in the Patent, namely three paragraphs of Example 10 and the closing part of Claim 19. Accordingly, the questions on which the contentions have tended to concentrate is whether those parts of the Patent were framed in good faith and with reasonable skill and knowledge.

81. HMR's contention is that the requirement in section 63(2) that "the specification" be drafted to the appropriate standard means that each and every part of the specification must be drafted to the appropriate standard, and, therefore, if the patentee fails to establish that each and every part of the specification has been drafted to the requisite standard, no damages, costs or expenses for any infringement of a patent can be granted. Amgen's argument is that, before section 63(2) can deprive the patentee of any damages, costs or expenses for infringement, the court must be satisfied (a) that, in light of the parts of the specification which are inaccurate, and in light of the parts of the specification which are satisfactory, that the specification viewed as a whole was not drafted to the requisite standard, and (b) that there is some sort of nexus between the parts of the specification which have been found to be invalid and whose drafting has fallen below the requisite standard, and the infringement which has been established, or would otherwise have been established.

82. On the one hand, as a matter of ordinary language, what appears to be required by Section 63(2) is a consideration of the skill and honesty devoted to the drafting of the whole of the specification, and not merely to a specific sentence or passage in the specification. In this connection, it is not very difficult to conceive a case where, for instance, a very long and detailed specification with many aspects and features can fairly be said, viewed as a whole, to have been drafted "with reasonable skill and knowledge" even though a couple of sentences, or even paragraphs, could be said to have fallen short of that standard.

83. On the other hand, it can be said with force that it cannot have been the intention of the 1977 Act that, particularly in a case involving a long and complex patent, the

parties or the Court should have to go through all the contents of the patent in order to check whether, taking into account the contents of every line, the specification as a whole was drafted with reasonable skill and care. Yet, on the literal reading of section 63(2), it could be said that such a pedantic approach to a patent is effectively required.

84. In my view, the correct approach, which appears to me to be consistent with the wording of section 63(2) and not inconsistent with the cases to which I have been referred, is as follows. One must inevitably initially concentrate or focus on the passages in the specification which are said to be inaccurate, and ask oneself whether they were framed in good faith and with reasonable skill and knowledge. If so, then the patentee has no problem under section 63(2). If they were not so framed, then the Court must ask itself whether, bearing in mind its conclusions as to the inadequacies of the patentee and its advisers in the drafting of the passages in question, the specification was "framed in good faith and with reasonable skill and knowledge".

85. In considering that issue, the importance of the specific passages which have been found to be inaccurate and in respect of which the patentee has fallen below the requisite standard is obviously a very important factor. Similarly, the degree to which the patentee and his advisers have fallen below the requisite standard of good faith, skill and/or knowledge in drafting the specific passage or passages may well affect the determination of whether or not the specification was drafted to the appropriate standard. A relatively small failure, which nonetheless represents a lack of reasonable skill, in relation to a minor passage in the specification, may well not be enough to prevent the patentee from establishing that the specification was drafted with reasonable skill. On the other hand, flagrant dishonesty in drafting an important passage in the specification may inevitably lead the court to conclude that the specification was not drafted in good faith. It must be a question of fact and degree in each case. I appreciate that this approach is less clear cut than that advanced by HMR, but it does seem to me to be more in accordance with the Statutory wording. It also appears to me that there is a strong case for saying that, while the court should

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certainly not be indulgent to the drafting of patents, it is not right that every time a patent manifests a single failure of skill or knowledge, section 63(2) is engaged.

86. However, I reject Amgen's case that there must be a nexus between the error and the infringement before section 63(2) can apply. First, it would involve implying a significant restriction into the sub-section, and this is something the court should not be prepared to do unless there is a compelling reason: no such reason has been made out. Secondly, it would involve an implication of a rather imprecise nature, which in some cases might be difficult to apply. In the present case, for instance, there could be said to be a nexus because HMR was alleged to infringe Claim 19, but there could equally be said to be no nexus, because I concluded that HMR infringe even if Claims 19 to 25 are excised. Thirdly, particularly if I am right about the effective absence of discretion in the case of a deleting amendment, the notion that section 63(2) represents a widely applicable sanction against a patentee who has drafted the specification ineptly or worse, appears to have real justification.

Section 62(3)

87. For completeness, I should mention that, in support of its case that Amgen should not be entitled to recover damages, expenses and costs, HMR, in addition to section 63(2), also relies on section 62(3). This provides:

> "Where an amendment of the specification... has been allowed under any of the provisions of this Act, no damages shall be awarded in proceedings for an infringement of the patent committed before the decision to allow the amendment unless the Court... is satisfied that the specifications of the patent as published was framed in good faith and with reasonable skill and knowledge."

88. HMR's argument, in so far as it relies on section 62(3), essentially fastens on the second paragraph of Example 10, whose deletion before the Appeal Board represented an amendment which was allowed in the past, and therefore could be said

to fall within section 62(3). HMR contends that the second paragraph of Example 10 was not "framed in good faith" or alternatively was not "framed... with reasonable skill and knowledge", and therefore, even if its argument in relation to the first paragraph of Example 10 based on section 63(2) fails, Amgen should nonetheless not be entitled to recover any damages from HMR until the decision of the Appeal Boards to allow the deletion of the second paragraph.

89. It does not appear to me that the issues on section 62(3) involve any points of principle which have not already been discussed in relation to section 63(2). Furthermore, given that I am considering the drafting of the second paragraph of Example 10 as error (c) under section 63(2), it does not seem to me that it is helpful to consider as a separate matter the question of Amgen's entitlement to relief in light of section 62(3).

THE ISSUES OF FACT AND INFERENCE

Introductory

90. The evidence and the arguments have centred on the knowledge and state of mind of Amgen and their advisers, and in particular their US patent agent, Mr Michael Borun, (a) at the time of the making of the fourth US Patent application around the end of November 1984, and (b) at the time of the first hearing before the Appeal Board in September 1994. November 1984 was the time when the three paragraphs were inserted for the first time into Example 10, namely on the filing of the fourth US Patent application, and they were required at that time to support the Claim which ultimately became Claim 19 of the Patent. It was this application which was the basis for the European Patent application, which was filed less than two weeks later. The reason for concentrating on Mr Borun is that it was his firm, now Marshal Gerstein & Borun, and he in particular, who took instructions from Amgen, and who ultimately drafted the US Patent applications.

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91. The reason for concentrating on the hearing before the Appeal Board in September 1994 is that it was at that stage that the contents of the first paragraph assumed particular importance. Between 1984 and 1988 nothing of great relevance occurred in relation to the Patent; between 1988 and 1994, the European Patent Office, through the Examining Division and Opposition Division, was content with a formulation of the relevant Claim which did not depend on the three paragraphs. However, at least according to HMR, it was the contents of the three paragraphs of Example 10 which enabled Amgen to retain Claim 19, albeit in an amended form, because, without the new limitation proposed in Auxiliary Request 11, the Appeal Board would not have upheld Claim 19, and that limitation was only justified by the contents of the first paragraph of Example 10. Again, Mr Borun is said by HMR to have been the centrally relevant individual, not only because he was present on behalf of Amgen at the hearing before the Appeal Board and had originally drafted the Patent, and in particular the three paragraphs, but also because, having acted for Amgen in the proceedings before the USPTO, the Chugai litigation, and the interference proceedings, he had obtained further highly relevant information.

92. In addition to the relevant documents, oral evidence was given by witnesses on behalf of Amgen. HMR elected to call no evidence. I heard from Mr Borun, Amgen's US patent attorney, and from Mr John Brown, the relevant partner in Amgen's European patent agents. In addition, I heard evidence from Mr Steven Odre, senior vice president and general counsel of Amgen, who had the in-house supervisory responsibility for the prosecution of the US and European patent applications. I also heard from Dr Thomas Strickland who had carried out experiments on behalf of Amgen, and gave evidence to the Appeal Board. Finally, I heard evidence from Mr David Bannerman, a partner, and since 1997 chairman, of patent agents, Withers & Rogers. He was called as an independent expert.

93. The most convenient way of dealing with the questions of whether any of the three errors involved a lack of reasonable skill and knowledge and/or a want of good faith, appears to me to be as follows. I shall first deal with whether error (a) involved at

least a want of reasonable skill and care in 1984. I shall then turn to deal with the same issue as at 1994 in relation to error (a). I shall then turn to error (b), which involves traversing much of the same ground. I shall then deal with error (c). Finally I shall deal with the question of whether any of the errors involved want of good faith.

Error (a) in 1984

94. Error (a) is in the first paragraph of Example 10, and involves concentrating on the information about the apparent molecular weights on SDS-PAGE of COS rEPO and urinary EPO. It seems clear that the person who had carried out the relevant experiments at Amgen was a member of D. Lin's team, Dr Joan Egrie, during 1984. Dr Egrie kept notebooks in which she contemporaneously recorded the results of experiments she carried out, including the relevant experiments in this connection.

95. At some point before he drafted the fourth US Patent application, it seems pretty clear that Mr Borun had a discussion with Dr Egrie about her work relating to the performance of various types of EPO's on SDS-PAGE, as a result of which she agreed to send him copies of relevant pages of her notebook. That is supported by a number of factors. First, Mr Borun had made up a file called "The Egrie input file" (which I shall call "the File") in his office, containing photocopies of pages from Dr Egrie's notebooks, and that seems to suggest that he asked her for them. Further, the first page of the File is a note dated 31st October 1984 (one month before the filing of the fourth US Patent application) in the handwriting of Mr Borun's assistant, referring to the fact that certain documents had been "requested by MFB" (i.e. Mr Borun). Thirdly, the second page of the File is a note from Dr Egrie to Mr Borun and his assistant stating that she "thought that the simplest thing to do was to xerox the relevant expts. for you out of our notebooks". Fourthly, in her deposition in the US infringement proceedings, Dr Egrie said that she thought that that is what happened. Further, while I did not find Mr Borun a satisfactory witness, the conclusion appears to be consistent with his evidence.

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