HOUSE OF LORDS SESSION 2003-04

[2004] UKHL 46

on appeal from: [2002] EWCA Civ 1096

OPINIONS

OF THE LORDS OF APPEAL

FOR JUDGMENT IN THE CAUSE

Kirin-Amgen Inc and others (Appellants) v. Hoechst Marion Roussel Limited and others (Respondents)

Kirin-Amgen Inc and others (Respondents) v. Hoechst Marion Roussel Limited and others (Appellants)

(Conjoined Appeals)

ON

THURSDAY 21 OCTOBER 2004

The Appellate Committee comprised:

Lord Hoffmann

Lord Hope of Craighead

Lord Rodger of Earlsferry

Lord Walker of Gestingthorpe

Lord Brown of Eaton-under-Heywood

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LORD HOFFMANN

My Lords,

The proceedings

1. Kirin-Amgen Inc ("Amgen"), a Californian pharmaceutical company, is the proprietor of a European patent (EP 0148605B2) relating to the production of erythropoietin ("EPO") by recombinant DNA technology. EPO is a hormone made in the kidney which stimulates the production of red blood cells by the bone marrow. The discovery by Amgen of a method of making EPO artificially for use as a drug was a significant advance in the treatment of anaemia, particularly when associated with kidney failure. Amgen market it under the name Epogen and the patent (which will expire on 11 December 2004) has been very profitable.

2. These appeals arise out of a dispute concerning both the validity and infringement of the patent between Amgen and two other pharmaceutical companies. Transkaryotic Therapies Inc ("TKT") is a Massachusetts corporation. It has also developed a method of making EPO, which it markets under the name Dynepo. It uses a process which it calls "gene activation" and the product been referred to in this appeal as "GA-EPO". Hoechst Marion Roussel Ltd ("Hoechst") is the English subsidiary of a well-known multinational pharmaceutical company which has been proposing to import GA-EPO into the United Kingdom. In three consolidated actions, Amgen claims that GA-EPO infringes the claims of the patent in suit and TKT and Hoechst claim a declaration of non-infringement and revocation of the patent. I shall for convenience refer to both Hoechst and TKT as "TKT" but it should be borne in mind that the only allegations of infringement in the United Kingdom arise out of the importation of the drug by Hoechst.

3. The science upon which recombinant DNA technology is based has been described in a number of judgments, not least in the admirable account given by Neuberger J in this case, much of which was reproduced verbatim by the Court of Appeal. I do not propose to repeat these passages but gratefully adopt them and will largely take them as read.

   The race for EPO

4. The technology for manufacturing proteins ("polypeptides") by the expression of recombinant DNA developed rapidly after the mid-1970s. The speed of development is illustrated by the decision of your Lordships' House in *Biogen Inc v Medeva plc* [1997] RPC 1, in which a recombinant method

of making the antigens of a hepatitis virus was patented with a priority date of 22 December 1978 but was conceded to have been obvious by 21 December 1979. Pharmaceutical companies competed to be the first to plant the flag on some desirable protein.

5. EPO was a particularly elusive goal in the early 1980s because it was difficult to get hold of enough of the natural product to do the necessary research. To design the probes to find the gene, whether in a genomic or cDNA library, you first had to know the amino acid sequence of at least a part of the natural polypeptide. But the kidney makes such minuscule quantities that purified natural EPO was virtually unobtainable. In 1977 a team including Dr Takaji Miyake and Dr Eugene Goldwasser developed and published a protocol for purifying milligrams of EPO from large quantities of urine laboriously collected from patients suffering from aplastic anaemia: see *Miyake et al*, 252 J Biol Chem. 252 No 15, pp 5558-5564 (1977). Dr Goldwasser made some of this urinary EPO ("uEPO") available to Dr Rodney Hewick of Cal Tech, who tried to sequence 26 residues at the N terminus. (The protein has 165 residues). This information was published by *Sue and Sytkowski* in 80 PNAS USA, pp 3651-3655 (1983) but two of the residues were incorrectly identified.

6. The Amgen team trying to sequence the EPO gene was headed by (indeed, consisted largely of) Dr Fu-Kuen Lin. Dr Goldwasser was engaged as a consultant. He was able to make some uEPO available to Dr Lin, who designed a set of fully degenerate probes to hybridise with the DNA coding for two regions of the protein. As the kidney makes so little EPO, there was little prospect of obtaining mRNA for a cDNA library. So Dr Lin used his probes on the vast array of genes in a genomic library. Against the odds, he obtained three positives which enabled him to locate the EPO gene in the fall of 1983. He was then able by patient but conventional methods to identify the whole of its structural region, its introns, exons and splicing sites and a fair amount of the upstream and downstream sequences as well. He thus established the correct sequence of the amino acid residues which formed the protein and its leader sequence.

7. This information, first discovered by Dr Lin, was essential to any process for making EPO, whether by Amgen's method or TKT's. As one of the principal issues in the case is whether TKT's GA-EPO (which is chemically exactly the same as Amgen's Epogen) falls outside the claims of the patent in suit because of the difference in the way it is made, I shall at once describe in bare outline the two methods. There are some details on which special arguments were founded and I shall come back to these later. For the moment, however, a sketch will do.

The two methods of making EPO

8. Once the sequence of the EPO gene had been discovered, it was possible to make it by methods of recombinant DNA technology which were well known in 1983. These are succinctly described in the specification of the

patent in suit:

> "Simply put, a gene that specifies the structure of a desired polypeptide product is either isolated from a 'donor' organism or chemically synthesised and then stably introduced into another organism which is preferably a self-replicating unicellular organism such as bacteria, yeast or mammalian cells in culture. Once this is done, the existing machinery for gene expression in the 'transformed' or 'transfected' microbial host cells operates to construct the desired product, using the exogenous DNA as a template for transcription of mRNA which is then translated into a continuous sequence of amino acid residues."

9. That is the way the patent in suit teaches how to make EPO. Dr Lin isolated the gene which coded for human EPO from a human donor cell and then introduced it into a mammalian cell in culture which had been derived from the ovary of a Chinese hamster (a "CHO cell"). As part of the hamster DNA, it expressed EPO. Of course it was not as simple as that. To get it into the DNA of the CHO cell, it had first to be incorporated into a bacterial plasmid vector. To improve the chances of expression, the gene's natural promoter was removed and a more powerful viral promoter substituted. To increase the rate of expression, cells in which the gene had been multiplied ("amplified") were selected by a technique which involved treating them with methotrexate. Indeed, the CHO cell had been chosen as host because it had a gene mutation which made it particularly suitable for amplification by methotrexate. But these were all tricks of the trade well known among practitioners of the art. The essence of the technique was that described in the passage from the specification which I have quoted, namely, the introduction of an exogenous DNA sequence coding for EPO into a host cell in which it would be expressed.

10. In TKT's gene activation method, the EPO is expressed in a human cell by an endogenous gene naturally present or by cells derived by replication from such a cell. Ordinarily, such a gene would not express EPO. Almost all human cells contain the full complement of DNA coding for all the proteins needed by the body ("the human genome") but each cell will express only those proteins which its particular tissue requires. The rest remain inactive, disabled by the absence of a suitable regulator which is needed to promote expression. The TKT technique involves introducing the necessary control sequence upstream of the EPO gene. The control sequence is accompanied by other bits of machinery (for example, to allow for amplification by methotrexate treatment) which it is for the moment unnecessary to describe. All this exogenous DNA has to be inserted into the human DNA at exactly the right point upstream of the EPO gene. This could not have been done at the time of the patent but can now be done by using a phenomenon called "homologous recombination". It is fully described by Neuberger J and I need say no more than that it enables TKT to activate or "switch on" the EPO gene in a human cell which would not ordinarily express that protein and then to select for commercial use those descendants of the manipulated cells in which the relevant genes have been amplified to produce a high level of

expression.

11. The essential difference between Epogen and GA-EPO is that the former is made by an exogenous DNA sequence coding for EPO which has been introduced into an host cell and the latter is made by an endogenous DNA sequence coding for EPO in a human cell into which an exogenous upstream control sequence has been inserted.

12. With that introduction, we can now look at the patent. The specification explains the relevant science, the nature of EPO and the difficulties which stood in the way of identifying the gene. It then describes the methods which Dr Lin used to find the gene in the DNA of monkeys and humans and sets out the full sequences for both species in Tables V and VI respectively. In a series of 12 examples it describes what Dr Lin was able to do with this information, including in example 7 the expression of human EPO in COS-1 cells (not very successful because of difficulties about amplification and transience of expression) and in example 10 its expression in CHO cells (successful because of amplification by methotrexate.) There are 31 claims but we need concern ourselves only with claims 1, 19 and 26. To summarise them very briefly and leaving out qualifications to which I shall later return, they are for (1) a DNA sequence for use in securing the expression of EPO in a host cell, (19) EPO which is the product of the expression of an exogenous DNA sequence and (26) EPO which is the product of the expression in a host cell of a DNA sequence according to claim 1. Only claims 19 and 26 are alleged to have been infringed because TKT do not make any GA-EPO in this country. The alleged infringement is by importation. But claim 26 cannot be understood without first construing claim 1.

13. I shall now set out the precise terms of the three relevant claims. Claim 1 is for?

> "A DNA sequence for use in securing expression in a procaryotic or eucaryotic host cell of a polypeptide product having at least part of the primary structural [conformation] of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells and to increase [haemoglobin] synthesis or iron uptake, said DNA sequence selected from the group consisting of:
>
> (a) the DNA sequences set out in Tables V and VI or their complementary strands;
>
> (b) DNA sequences which hybridize under stringent conditions to the protein coding regions of the DNA sequences defined in (a) or fragments thereof; and
>
> (c) DNA sequences which, but for the degeneracy of the genetic code, would hybridize to the DNA sequences defined in (a) and (b)."

14. Claim 19 is for?

> "A recombinant polypeptide having part or all of the primary structural conformation of human or monkey erythropoietin as set forth in Table VI or Table V or any allelic variant or derivative thereof possessing the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells to increase haemoglobin synthesis or iron uptake and characterised by being the product of eucaryotic expression of an exogenous DNA sequence and which has a higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources."

15. Finally, claim 26 is for?

> "A polypeptide product of the expression in a eucaryotic host cell of a DNA sequence according to any of claims 1, 2, 3, 5, 6 and 7."

16. Claims 2, 3, 5, 6 and 7 are all dependent on claim 1 in the sense that if the TKT method does not involve using a "DNA sequence for use in securing expression [of EPO] in a…host cell" within the meaning of claim 1, it would not infringe any of the other claims either.

The decisions of the courts below

17. The trial judge held that claim 19 was invalid (for insufficiency) but that claim 26 was valid and infringed. The Court of Appeal (Aldous, Hale and Latham LJJ) held that both claims were valid but that neither was infringed. Both sides appeal: Amgen against the decision that, as a matter of construction, the TKT process is not within the claims and TKT against the rejection of its attack on the claims for insufficiency and (in the case of claim 26) anticipation. I shall consider Amgen's appeal first.

Extent of protection: the statutory provisions

18. Until the Patents Act 1977, which gave effect to the European Patent Convention ("EPC") there was nothing in any UK statute about the extent of protection conferred by a patent. It was governed by the common law, the terms of the royal grant and general principles of construction. It was these principles which Lord Diplock expounded in the leading case of *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, which concerned a patent granted before 1977. But the EPC and the Act deal expressly with the matter in some detail. Article 84 specifies the role of the claims in an application to the European Patent Office for a European patent:

> "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."

19. For present purposes, the most important provision is article 69 of the EPC, which applies to infringement proceedings in the domestic courts of all

Contracting States:

> "The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims."

20. In stating unequivocally that the extent of protection shall be "determined" (in German, "*bestimmt*") by the "terms of the claims" (*den Inhalt der Patentansprüche*) the Convention followed what had long been the law in the United Kingdom. During the course of the 18th and 19th centuries, practice and common law had come to distinguish between the part of the specification in which the patentee discharged his duty to disclose the best way of performing the invention and the section which delimited the scope of the monopoly which he claimed: see Fletcher-Moulton LJ in *British United Shoe Machinery Co Ltd v A. Fussell & Sons Ltd* (1908) 25 RPC 631, 650. The best-known statement of the status of the claims in UK law is by Lord Russell of Killowen in *Electric and Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 39:

> "The function of the claims is to define clearly and with precision the monopoly claimed, so that others may know the exact boundary of the area within which they will be trespassers. Their primary object is to limit and not to extend the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire document and not as a separate document; but the forbidden field must be found in the language of the claims and not elsewhere."

21. The need to set clear limits upon the monopoly is not only, as Lord Russell emphasised, in the interests of others who need to know the area "within which they will be trespassers" but also in the interests of the patentee, who needs to be able to make it clear that he lays no claim to prior art or insufficiently enabled products or processes which would invalidate the patent.

22. In Germany, however, the practice before 1977 in infringement proceedings (validity is determined by a different court) was commonly to treat the claims as a point of departure ("*Ausgangspunkt*") in determining the extent of protection, for which the criterion was the inventive achievement ("*erfinderische Leistung*") disclosed by the specification as a whole. Likewise in the Netherlands, Professor Jan Brinkhof, former Vice-President of the Hague Court of Appeals, has written that the role of the claims before 1977 was "extremely modest": see *Is there a European Doctrine of Equivalence?* (2002) 33 IIC 911, 915. What mattered was the "essence of the invention" or what we would call the inventive concept.

The Protocol

23. Although the EPC thus adopted the United Kingdom principle of using the claims to determine the extent of protection, the Contracting States were

unwilling to accept what were understood to be the principles of construction which United Kingdom courts applied in deciding what the claims meant. These principles, which I shall explain in greater detail in a moment, were perceived as having sometimes resulted in claims being given an unduly narrow and literal construction. The Contracting Parties wanted to make it clear that legal technicalities of this kind should be rejected. On the other hand, it was accepted that countries which had previously looked to the "essence of the invention" rather than the actual terms of the claims should not carry on exactly as before under the guise of giving the claims a generous interpretation.

24. This compromise was given effect by the "Protocol on the Interpretation of Article 69":

> "Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties."

25. It is often said, on the basis of the words "a position between these extremes", that the Protocol represents a compromise between two different approaches to the interpretation of claims. But that is not quite accurate. It is a protocol on the interpretation of article 69, not a protocol on the interpretation of claims. The first sentence does deal with interpretation of the claims and, to understand it, one needs to know something about the rules which English courts used to apply, or impose on themselves, when construing not merely patents but documents in general. The second sentence does not deal with the interpretation of claims. Instead, it makes it clear that one cannot go beyond the claims to what, on the basis of the specification as a whole, it appears that "the patentee has contemplated". But the last sentence indicates that, in determining the extent of protection according to the content of the claims but avoiding literalism, the courts of the Contracting States should combine "a fair protection for the patentee with a reasonable degree of certainty for third parties."

26. Both article 69 and the Protocol are given effect in United Kingdom law, in relation to infringement, by sections 60 and 125 of the Act. Section 60 provides that a person infringes a patent if he does various things in the United Kingdom "in relation to the invention" without the consent of the proprietor of the patent. Section 125 defines the extent of "the invention":

> "(1) For the purpose of this Act an invention for a patent for which

> an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.
>
> (3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article."

The English rules of construction

27. As I indicated a moment ago, it is impossible to understand what the first sentence of the Protocol was intending to prohibit without knowing what used to be the principles applied (at any rate in theory) by an English court construing a legal document. These required the words and grammar of a sentence to be given their "natural and ordinary meaning", that is to say, the meanings assigned to the words by a dictionary and to the syntax by a grammar. This meaning was to be adopted regardless of the context or background against which the words were used, unless they were "ambiguous", that is to say, capable of having more than one meaning. As Lord Porter said in *Electric & Musical Industries Ltd v Lissen Ltd* (1938) 56 RPC 23, 57:

> "If the Claims have a plain meaning *in themselves* [emphasis supplied], then advantage cannot be taken of the language used in the body of the Specification to make them mean something different."

28. On the other hand, if the language of the claim "in itself" was ambiguous, capable of having more than one meaning, the court could have regard to the context provided by the specification and drawings. If that was insufficient to resolve the ambiguity, the court could have regard to the background, or what was called the "extrinsic evidence" of facts which an intended reader would reasonably have expected to have been within the knowledge of the author when he wrote the document.

29. These rules, if remorselessly applied, meant that unless the court could find some ambiguity in the language, it might be obliged to construe the document in a sense which a reasonable reader, aware of its context and background, would not have thought the author intended. Such a rule, adopted in the interests of certainty at an early stage in the development of English law, was capable of causing considerable injustice and occasionally did so. The fact that it did not do so more often was because judges were generally astute to find the necessary "ambiguity" which enabled them to interpret the document in its proper context. Indeed, the attempt to treat the words of the claim as having meanings "in themselves" and without regard

to the context in which or the purpose for which they were used was always a highly artificial exercise.

30. It seems to me clear that the Protocol, with its reference to "resolving an ambiguity", was intended to reject these artificial English rules for the construction of patent claims. As it happens, though, by the time the Protocol was signed, the English courts had already begun to abandon them, not only for patent claims, but for commercial documents generally. The speeches of Lord Wilberforce in *Prenn v Simmonds* [1971] 1 WLR 1381 and *Reardon Smith Line Ltd. v Yngvar Hansen-Tangen* [1976] 1 WLR 989 are milestones along this road. It came to be recognised that the author of a document such as a contract or patent specification is using language to make a communication for a practical *purpose* and that a rule of construction which gives his language a meaning different from the way it would have been understood by the people to whom it was actually addressed is liable to defeat his intentions. It is against that background that one must read the well known passage in the speech of Lord Diplock in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183, 243 when he said that the new approach should also be applied to the construction of patent claims:

> "A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge."

31. This was all of a piece with Lord Diplock's approach a few years later in *The Antaios* [1985] AC 191, 201 to the construction of a charterparty:

> "I take this opportunity of re-stating that if detailed semantic and syntactical analysis of words in a commercial contract is going to lead to a conclusion that flouts business commonsense, it must be made to yield to business commonsense."

32. Construction, whether of a patent or any other document, is of course not directly concerned with what the author meant to say. There is no window into the mind of the patentee or the author of any other document. Construction is objective in the sense that it is concerned with what a reasonable person to whom the utterance was addressed would have understood the author to be using the words to mean. Notice, however, that it is not, as is sometimes said, "the meaning of the words the author used", but rather what the notional addressee would have understood the *author* to mean by using those words. The meaning of words is a matter of convention, governed by rules, which can be found in dictionaries and grammars. What the author would have been understood to mean by using those words is not simply a matter of rules. It is highly sensitive to the context of and background to the particular utterance. It depends not only upon the words the author has chosen but also upon the identity of the audience he is taken to have been addressing and the knowledge and assumptions which one attributes to that audience. I have discussed these questions at some length in *Mannai Investment Co Ltd v Eagle Star Life*

Assurance Co Ltd [1997] AC 749 and *Investors Compensation Scheme Ltd v West Bromwich Building Society* [1998] 1 WLR 896.

33. In the case of a patent specification, the notional addressee is the person skilled in the art. He (or, I say once and for all, she) comes to a reading of the specification with common general knowledge of the art. And he reads the specification on the assumption that its purpose is to both to describe and to demarcate an invention - a practical idea which the patentee has had for a new product or process - and not to be a textbook in mathematics or chemistry or a shopping list of chemicals or hardware. It is this insight which lies at the heart of "purposive construction". If Lord Diplock did not invent the expression, he certainly gave it wide currency in the law. But there is, I think, a tendency to regard it as a vague description of some kind of divination which mysteriously penetrates beneath the language of the specification. Lord Diplock was in my opinion being much more specific and his intention was to point out that a person may be taken to mean something different when he uses words for one purpose from what he would be taken to mean if he was using them for another. The example in the *Catnic* case was the difference between what a person would reasonably be taken to mean by using the word "vertical" in a mathematical theorem and by using it in a claimed definition of a lintel for use in the building trade. The only point on which I would question the otherwise admirable summary of the law on infringement in the judgment of Jacob LJ in *Rockwater Ltd v Technip France SA* (unreported) [2004] EWCA Civ 381, at paragraph 41, is when he says in sub-paragraph (e) that to be "fair to the patentee" one must use "the widest purpose consistent with his teaching". This, as it seems to me, is to confuse the *purpose* of the utterance with what it would be understood to *mean*. The purpose of a patent specification, as I have said, is no more nor less than to communicate the idea of an invention. An appreciation of that purpose is part of the material which one uses to ascertain the meaning. But purpose and meaning are different. If, when speaking of the widest purpose, Jacob LJ meant the widest meaning, I would respectfully disagree. There is no presumption about the width of the claims. A patent may, for one reason or another, claim less than it teaches or enables.

34. "Purposive construction" does not mean that one is extending or going beyond the definition of the technical matter for which the patentee seeks protection in the claims. The question is always what the person skilled in the art would have understood the patentee to be using the language of the claim to mean. And for this purpose, the language he has chosen is usually of critical importance. The conventions of word meaning and syntax enable us to express our meanings with great accuracy and subtlety and the skilled man will ordinarily assume that the patentee has chosen his language accordingly. As a number of judges have pointed out, the specification is a unilateral document in words of the patentee's own choosing. Furthermore, the words will usually have been chosen upon skilled advice. The specification is not a document *inter rusticos* for which broad allowances must be made. On the other hand, it must be recognised that the patentee is trying to describe something which, at any rate in his opinion, is new; which

has not existed before and of which there may be no generally accepted definition. There will be occasions upon which it will be obvious to the skilled man that the patentee must in some respect have departed from conventional use of language or included in his description of the invention some element which he did not mean to be essential. But one would not expect that to happen very often.

35. One of the reasons why it will be unusual for the notional skilled man to conclude, after construing the claim purposively in the context of the specification and drawings, that the patentee must nevertheless have meant something different from what he appears to have meant, is that there are necessarily gaps in our knowledge of the background which led him to express himself in that particular way. The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life is too short for the limited assistance which it can provide. It is however frequently impossible to know without access, not merely to the file but to the private thoughts of the patentee and his advisors as well, what the reason was for some apparently inexplicable limitation in the extent of the monopoly claimed. One possible explanation is that it does not represent what the patentee really meant to say. But another is that he did mean it, for reasons of his own; such as wanting to avoid arguments with the examiners over enablement or prior art and have his patent granted as soon as possible. This feature of the practical life of a patent agent reduces the scope for a conclusion that the patentee could not have meant what the words appear to be saying. It has been suggested that in the absence of any explanation for a restriction in the extent of protection claimed, it should be presumed that there was some good reason between the patentee and the patent office. I do not think that it is sensible to have presumptions about what people must be taken to have meant but a conclusion that they have departed from conventional usage obviously needs some rational basis.

The doctrine of equivalents

36. At the time when the rules about natural and ordinary meanings were more or less rigidly applied, the United Kingdom and American courts showed understandable anxiety about applying a construction which allowed someone to avoid infringement by making an "immaterial variation" in the invention as described in the claims. In England, this led to the development of a doctrine of infringement by use of the "pith and marrow" of the invention (a phrase invented by Lord Cairns in *Clark v Adie* (1877) 2 App Cas 315, 320) as opposed to a "textual infringement". The pith and marrow doctrine was always a bit vague ("necessary to prevent sharp practice" said Lord Reid in *C Van Der Lely NV v Bamfords* Ltd [1963] RPC 61, 77) and it was unclear whether the courts regarded it as a principle of construction or an extension of protection outside the claims.

37. In the United States, where a similar principle is called the "doctrine of

equivalents", it is frankly acknowledged that it allows the patentee to extend his monopoly beyond the claims. In the leading case of *Graver Tank & Manufacturing Co Inc v Linde Air Products Company* 339 US 605, 607 (1950), Jackson J said that the American courts had recognised?

> "that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for - indeed encourage - the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law."

38. In similar vein, Learned Hand J (a great patent lawyer) said that the purpose of the doctrine of equivalents was "to temper unsparing logic and prevent an infringer from stealing the benefit of the invention": *Royal Typewriter Co v Remington Rand Inc* (CA2nd Conn) 168 F2nd 691, 692. The effect of the doctrine is thus to extend protection to something outside the claims which performs substantially the same function in substantially the same way to obtain the same result.

39. However, once the monopoly had been allowed to escape from the terms of the claims, it is not easy to know where its limits should be drawn. In *Warner-Jenkinson Co v Hilton Davis Chemical Co* 520 US 17, 28-29 (1997) the United States Supreme Court expressed some anxiety that the doctrine of equivalents had "taken on a life of its own, unbounded by the patent claims." It seems to me, however, that once the doctrine is allowed to go beyond the claims, a life of its own is exactly what it is bound to have. The American courts have restricted the scope of the doctrine by what is called prosecution history or file wrapper estoppel, by which equivalence cannot be claimed for integers restricting the monopoly which have been included by amendment during the prosecution of the application in the patent office. The patentee is estopped against the world (who need not have known of or relied upon the amendment) from denying that he intended to surrender that part of the monopoly. File wrapper estoppel means that the true scope of patent protection often cannot be established without an expensive investigation of the patent office file. Furthermore, the difficulties involved in deciding exactly what part of the claim should be taken to have been withdrawn by an amendment drove the Federal Court of Appeals in *Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Co Ltd* 234 F3rd 558 (2000) to declare that the law was arbitrary and unworkable. Lourie J said:

> "The only settled expectation currently existing is the expectation that clever attorneys can argue infringement outside the scope of the claims all the way through this Court of Appeals."

40. In order to restore some certainty, the Court of Appeals laid down a rule that any amendment for reasons of patent validity was an absolute bar to any extension of the monopoly outside the literal meaning of the amended text. But the Supreme Court reversed this retreat to literalism on the ground that

the cure was worse than the disease: see *Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Co Ltd* (28 May 2002) US Supreme Court.

41. There is often discussion about whether we have a European doctrine of equivalents and, if not, whether we should. It seems to me that both the doctrine of equivalents in the United States and the pith and marrow doctrine in the United Kingdom were born of despair. The courts felt unable to escape from interpretations which "unsparing logic" appeared to require and which prevented them from according the patentee the full extent of the monopoly which the person skilled in the art would reasonably have thought he was claiming. The background was the tendency to literalism which then characterised the approach of the courts to the interpretation of documents generally and the fact that patents are likely to attract the skills of lawyers seeking to exploit literalism to find loopholes in the monopoly they create. (Similar skills are devoted to revenue statutes).

42. If literalism stands in the way of construing patent claims so as to give fair protection to the patentee, there are two things that you can do. One is to adhere to literalism in construing the claims and evolve a doctrine which supplements the claims by extending protection to equivalents. That is what the Americans have done. The other is to abandon literalism. That is what the House of Lords did in the *Catnic* case, where Lord Diplock said (at [1982] RPC 183, 242:

> "Both parties to this appeal have tended to treat 'textual infringement' and infringement of the 'pith and marrow' of an invention as if they were separate causes of action, the existence of the former to be determined as a matter of construction only and of the latter upon some broader principle of colourable evasion. There is, in my view, no such dichotomy; there is but a single cause of action and to treat it otherwise…is liable to lead to confusion."

43. The solution, said Lord Diplock, was to adopt a principle of construction which actually gave effect to what the person skilled in the art would have understood the patentee to be claiming.

44. Since the *Catnic* case we have article 69 which, as it seems to me, firmly shuts the door on any doctrine which extends protection outside the claims. I cannot say that I am sorry because the *Festo* litigation suggests, with all respect to the courts of the United States, that American patent litigants pay dearly for results which are no more just or predictable than could be achieved by simply reading the claims.

Is Catnic consistent with the Protocol?

45. In *Improver Corp v Remington Consumer Products Ltd* [1989] RPC 69 the Court of Appeal said that Lord Diplock's speech in *Catnic* advocated the same approach to construction as is required by the Protocol. (See also *Southco Inc v Dzus Fastener Europe Ltd* [1992] RPC 299.) But in *PLG Research Ltd v Ardon International Ltd* [1995] RPC 287, 309 Millett LJ

said:

> "Lord Diplock was expounding the common law approach to the construction of a patent. This has been replaced by the approach laid down by the Protocol. If the two approaches are the same, reference to Lord Diplock's formulation is unnecessary, while if they are different it is dangerous."

46. This echoes, perhaps consciously, the famous justification said to have been given by the Caliph Omar for burning the library of Alexandria: "If these writings of the Greeks agree with the Book of God, they are useless and need not be preserved: if they disagree, they are pernicious and ought to be destroyed" - a story which Gibbon dismissed as Christian propaganda. But I think that the Protocol can suffer no harm from a little explanation and I entirely agree with the masterly judgment of Aldous J in *Assidoman Multipack Ltd v The Mead Corporation* [1995] RPC 321, in which he explains why the *Catnic* approach accords with the Protocol.

47. The Protocol, as I have said, is a Protocol for the construction of article 69 and does not expressly lay down any principle for the construction of claims. It does say what principle should *not* be followed, namely the old English literalism, but otherwise it says only that one should not go outside the claims. It does however say that the object is to combine a fair protection for the patentee with a reasonable degree of certainty for third parties. How is this to be achieved? The claims must be construed in a way which attempts, so far as is possible in an imperfect world, not to disappoint the reasonable expectations of either side. What principle of interpretation would give fair protection to the patentee? Surely, a principle which would give him the full extent of the monopoly which the person skilled in the art would think he was intending to claim. And what principle would provide a reasonable degree of protection for third parties? Surely again, a principle which would not give the patentee more than the full extent of the monopoly which the person skilled in the art would think that he was intending to claim. Indeed, any other principle would also be unfair to the patentee, because it would unreasonably expose the patent to claims of invalidity on grounds of anticipation or insufficiency.

48. The *Catnic* principle of construction is therefore in my opinion precisely in accordance with the Protocol. It is intended to give the patentee the full extent, but not more than the full extent, of the monopoly which a reasonable person skilled in the art, reading the claims in context, would think he was intending to claim. Of course it is easy to say this and sometimes more difficult to apply it in practice, although the difficulty should not be exaggerated. The vast majority of patent specifications are perfectly clear about the extent of the monopoly they claim. Disputes over them never come to court. In borderline cases, however, it does happen that an interpretation which strikes one person as fair and reasonable will strike another as unfair to the patentee or unreasonable for third parties. That degree of uncertainty is inherent in any rule which involves the construction of any document. It afflicts the whole of the law of contract, to say nothing

of legislation. In principle it is without remedy, although I shall consider in a moment whether uncertainty can be alleviated by guidelines or a "structured" approach to construction.

Equivalents as a guide to construction

49. Although article 69 prevents equivalence from extending protection outside the claims, there is no reason why it cannot be an important part of the background of facts known to the skilled man which would affect what he understood the claims to mean. That is no more than common sense. It is also expressly provided by the new article 2 added to the Protocol by the Munich Act revising the EPC, dated 29 November 2000 (but which has not yet come into force):

> "For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims."

50. In the *Catnic* case [1982] RPC 183, 243 Lord Diplock offered some observations on the relevance of equivalence to the question of construction:

> "The question in each case is: whether persons with practical knowledge and experience of the kind of work in which the invention was intended to be used, would understand that strict compliance with a particular descriptive word or phrase appearing in a claim was intended by the patentee to be an essential requirement of the invention so that *any* variant would fall outside the monopoly claimed, even though it could have no material effect upon the way the invention worked.
>
> The question, of course, does not arise where the variant would in fact have a material effect upon the way the invention worked. Nor does it arise unless at the date of publication of the specification it would be obvious to the informed reader that this was so. Where it is not obvious, in the light of then-existing knowledge, the reader is entitled to assume that the patentee thought at the time of the specification that he had good reason for limiting his monopoly so strictly and had intended to do so, even though subsequent work by him or others in the field of the invention might show the limitation to have been unnecessary. It is to be answered in the negative only when it would be apparent to any reader skilled in the art that a particular descriptive word or phrase used in a claim cannot have been intended by a patentee, who was also skilled in the art, to exclude minor variants which, to the knowledge of both him and the readers to whom the patent was addressed, could have no material effect upon the way in which the invention worked."

51. In *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181, 189 I tried to summarise this guidance:

> "If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim ("a variant") was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:
>
> (1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no?
>
> (2) Would this (ie that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes?
>
> (3) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.
>
> On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which include the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class."

52. These questions, which the Court of Appeal in *Wheatly v Drillsafe Ltd* [2001] RPC 133, 142 dubbed "the Protocol questions" have been used by English courts for the past fifteen years as a framework for deciding whether equivalents fall within the scope of the claims. On the whole, the judges appear to have been comfortable with the results, although some of the cases have exposed the limitations of the method. When speaking of the "*Catnic* principle" it is important to distinguish between, on the one hand, the principle of purposive construction which I have said gives effect to the requirements of the Protocol, and on the other hand, the guidelines for applying that principle to equivalents, which are encapsulated in the Protocol questions. The former is the bedrock of patent construction, universally applicable. The latter are only guidelines, more useful in some cases than in others. I am bound to say that the cases show a tendency for counsel to treat the Protocol questions as legal rules rather than guides which will in appropriate cases help to decide what the skilled man would have understood the patentee to mean. The limits to the value of the guidelines are perhaps most clearly illustrated by the present case and therefore, instead of discussing the principles in the abstract as I have been doing so far, I shall make my comments by reference to the facts of the case.

The judge's construction of the claims

53. It will be recalled that claim 1 is to a DNA sequence, selected from the sequences set out in Table VI or related sequences, for securing the expression of EPO in a "host cell". The chief question of construction is

whether the person skilled in the art would understand "host cell" to mean a cell which is host to the DNA sequence which coded for EPO. The alternative, put forward by Amgen, is that it can include a sequence which is endogenous to the cell, like the human EPO gene which expresses GA-EPO, as long as the cell is host to some exogenous DNA. In the TKT process, it is host to the control sequence and other machinery introduced by homologous recombination.

54. On this question, the judge had the advantage of hearing the evidence of a number of witnesses who were highly skilled in the art. They all said that they would have understood claim 1 to be referring to a DNA sequence coding for EPO which had been isolated or synthesised and was suitable for expression in a host cell. In other words, the claim was to a sequence coding for EPO which was exogenous to the cell in which expression took place. The judge summed up his conclusions in paragraph 215:

> "I am of the view that a cell is not a 'host cell' unless it is host to exogenous DNA encoding for EPO or its analogue. Such a conclusion is based in part on the teaching of the [patent in suit]. The terms 'host' and 'host cell' are used consistently to describe cells which have been transfected with exogenous or foreign DNA (ie DNA from outside that particular cell) which encodes EPO, with a view to securing expression of EPO in those host cells. That was accepted by [Amgen's expert] Dr Brenner. The examples contained in the [patent in suit] are all concerned with EPO-encoding DNA which has been isolated outside the cell and inserted into the cell to which it is foreign. Indeed, at the relevant time, the routine method of production of a recombinant protein was by cloning the gene encoding the protein and the introduction of that clone into a self-replicating organism by transfection or transformation. There was no knowledge of the technique of 'switching on' an endogenous encoding sequence by transfecting the cell with exogenous DNA sequences as including an artificial promoter."

55. Besides these general considerations, the judge relied upon other indications in the language of the specification. The words "for use in securing expression … of a polypeptide" suggested the DNA which coded for that polypeptide rather than a control sequence which promoted expression of endogenous DNA. That was supported by paragraph (b) of claim 1, which extended the claim to sequences which were not in Table VI but which hybridised under stringent conditions to "the protein coding regions" of Table VI.

56. Furthermore, the specification appears anxious to point out that the invention covers the use of mammalian cells which already have an EPO gene of their own:

> "It will be understood that expression of, eg, monkey origin DNA in monkey host cells in culture and human host cells in culture, actually constitute instances of 'exogenous' DNA expression inasmuch as the

EPO DNA whose high level expression is sought would not have its origins in the genome of the host."

57. That certainly suggests that the patentee regarded it as essential to his invention that the DNA of which high level expression was sought should not have its origin in the genome of the host cell. That would clearly exclude the DNA sequence which expresses GA-EPO, which forms part of the genome of the host cell.

58. For these reasons, which I find entirely convincing, the judge came to the conclusion that the person skilled in the art would not regard the endogenous coding sequence which expressed GA-EPO as falling within claim 1. It followed that GA-EPO was not the expression of a DNA sequence within claim 1 and therefore did not infringe claim 26. And by the same process of reasoning, the judge concluded that the person skilled in the art would not regard GA-EPO as "the product of … expression of an exogenous DNA sequence" within claim 19. At this point in the judgment, TKT might have concluded that they had won. I shall return in a moment to consider why the judge nevertheless held claim 26 to have been infringed. But, first, I must dea1 with three criticisms of the judge's construction advanced by Mr Watson QC on behalf of Amgen.

59. First, Mr Watson says that in construing claim 1, the judge has read "a DNA sequence" to mean "an exogenous DNA sequence encoding for EPO" and thereby read into the claim words which are not there. Similarly in claim 26 he has read "expression … of a DNA sequence" to mean "expression of an exogenous DNA sequence coding for EPO". But in my opinion no words have been "read into" the claims. The meaning of the term "host cell" is wholly dependent on context. The notion of a host entails the notion of a guest. If the guest is not expressly identified, it must be inferred from context. One answer might have been that the guest was intended to be any DNA whatever. In that case, TKT's human cells are host to the sequences inserted by homologous recombination. But the judge has held, in my opinion rightly, that "host cell" in the context of the specification means "cell which is host to an exogenous DNA sequence encoding for EPO". This is not reading words into the claim any more than when one says that in a particular context "the City" means "the City of London."

60. Secondly, Mr Watson submits that the judge assumed that GA-EPO was made by the human cells (HT-1080) in which the EPO gene was endogenous. In fact, it was made by the R-223 cells selected by methotrexate by reason of their amplification of the gene. Such amplification would not have occurred without the introduction of the exogenous DNA upstream of the EPO gene in the original cells.

61. This seems to me a lawyer's point if ever there was one. The claims are concerned with the expression of EPO by a gene which is exogenous to the cell. But the genes which express EPO in the R-223 cells are not exogenous. They come into existence when the cell is formed by division and simply replicate the genes in the HT-1080 cells. The fact that exogenous DNA is

needed to promote amplification seems to me irrelevant.

62. Thirdly, Mr Watson submits that a part of the EPO encoding sequence *was* exogenous to the cell. For reasons into which it is unnecessary to inquire, the TKT process removed 13 nucleotides from the beginning of the leader sequence in the natural gene and substituted ten others. But the amino acid residues for which these nucleotides coded were removed during the process of expression and formed no part of the mature protein. The EPO to which the claims refer is in my opinion the mature protein which was entirely encoded by endogenous DNA.

The judge's application of the Protocol questions

63. Having thus construed the claims, the judge described his construction as "literal" and moved on to the Protocol questions. In what sense could the construction have been literal? The first difficulty about the application of the Protocol questions is to decide what is meant by a "primary, literal or acontextual meaning". The judge's construction could not possibly be described as acontextual. It was entirely dependent on context and reflected the evidence of how the claim would have been understood by men skilled in the art.

64. No one has ever made an acontextual statement. There is always some context to any utterance, however meagre. "Acontextual meaning" can refer only to the conventional rules for the use of language, such as one finds in a dictionary or grammar. But then, to compare acontextual meaning in that sense with contextual meaning is to compare apples with pears. The one refers to a general rule about how words or syntax *should* be used and the other to the fact of what on a specific occasion the language *was* used to mean. So, to make any sense of the terms "primary, literal or acontextual meaning" in the Protocol questions, it must be taken to mean a construction which assumes that the author used words strictly in accordance with their conventional meanings.

65. The notion of strict compliance with the conventional meanings of words or phrases sits most comfortably with the use of figures, measurements, angles and the like, when the question is whether they allow for some degree of tolerance or approximation. That was the case in *Catnic* and it is significant that the "quintet" of cases in which the German Bundesgerichtshof referred to *Catnic* and said that its approach accorded with that of the House of Lords were all concerned with figures and measurements. In such cases, the contrast with strict compliance is approximation and not the rather pretentious figures of speech mentioned in the Protocol questions.

66. No doubt there are other cases, not involving figures or measurements, in which the question is whether a word or phrase was used in a strictly conventional or some looser sense. But the present case illustrates the difficulty of applying the Protocol questions when no such question arises. No one suggests that "an exogenous DNA sequence coding for EPO" can

have some looser meaning which includes "an endogenous DNA sequence coding for EPO". The question is rather whether the person skilled in the art would understand the invention as operating at a level of generality which makes it irrelevant whether the DNA which codes for EPO is exogenous or not. That is a difficult question to put through the mangle of the Protocol questions because the answer depends entirely upon what you think the invention is. Once you have decided that question, the Protocol questions answer themselves.

67. The judge thought that the invention was the discovery of the sequence of the EPO gene and the associated information. It followed that any method of making EPO which used that information, whether by the expression of exogenous or endogenous DNA, would operate in the same way and that this would be obvious to the person skilled in the art. Furthermore, there was no reason why the patentee should have wished to insist upon any particular method of using the information to obtain the expression of EPO.

68. The Court of Appeal, on the other hand, thought that the invention was a way of making EPO. The information about the sequence of the gene was necessary to enable the invention to be performed but was not and could not be the invention itself. It followed that a different way of making EPO worked in a different way from that described in the invention and that this would have been obvious to a person skilled in the art. The Court of Appeal added that if they had answered the first two Protocol questions in favour of Amgen they would also have answered the third in its favour. That is a somewhat unreal hypothesis and seems only to mean that if upon the true construction of the claims the invention was broad enough to include any method of making EPO, they would not have understood the patentee to be insisting on any particular method.

69. I shall say in a moment why I agree with the Court of Appeal, but I want first to emphasise a point I have already made about the use of the Protocol questions. The determination of the extent of protection conferred by a European patent is an examination in which there is only one compulsory question, namely that set by article 69 and its Protocol: what would a person skilled in the art have understood the patentee to have used the language of the claim to mean? Everything else, including the Protocol questions, is only guidance to a judge trying to answer that question. But there is no point in going through the motions of answering the Protocol questions when you cannot sensibly do so until you have construed the claim. In such a case - and the present is in my opinion such a case - they simply provide a formal justification for a conclusion which has already been reached on other grounds.

70. I agree with the Court of Appeal that the invention should normally be taken as having been claimed at the same level of generality as that at which it is defined in the claims. It would be unusual for the person skilled in the art to understand a specification to be claiming an invention at a higher level of generality than that chosen by the patentee. That means that once the judge had construed the claims as he did, he had answered the question of

infringement. It could only cause confusion to try to answer the Protocol questions as well.

71. No doubt there will be patent lawyers who are dismayed at the notion that the Protocol questions do not provide an answer in every case. They may feel cast adrift on a sea of interpretative uncertainty. But that is the fate of all who have to understand what people mean by using language. The Protocol questions are useful in many cases, but they are not a substitute for trying to understand what the person skilled in the art would have understood the patentee to mean by the language of the claims.

72. This is perhaps an appropriate point at which to mention what may appear to be a difference between the German, United Kingdom and Netherlands approach to these questions. It used to be thought that despite article 69 and the Protocol, there remained serious differences between the approaches to construction of the United Kingdom on the one hand and Germany and the Netherlands on the other. And it is true that in the early years of the EPC, there was a view in the German and Netherlands courts that the Convention had made no difference and that the Protocol entitled the courts of Contracting States to go on deciding the extent of protection exactly as before. The position in the Netherlands is described by Professor Brinkhof in the article *Is there a European Doctrine of Equivalence?* (2002) IIC 911 to which I have already referred.

73. But I do not think that this is any longer true. The highest courts in both Germany (see *Batteriekastenschnur* [1989] GRUR 903, 904) and the Netherlands (see *Ciba-Geigy/Oté Optics* (1995) *Nederlandse Jurisprudentie* 39) have said that the effect of article 69 is to give the claims what the European Patent Office has called a "central role": see *BAYER/Plant growth regulating agent* [1990] EPOR 257, 261. The Bundesgerichtshof said in the *Batteriekastenschnur* case that the claims are no longer merely a point of departure but the decisive basis (*maßgebliche Grundlage*) for determining the extent of protection.

74. In addressing the 10th Symposium of European Patent Judges in Luxembourg in 2000, the distinguished German patent lawyer Dr Rüdiger Rogge (then presiding judge of the 10th (intellectual property) Senate of the Bundesgerichtshof) said that he regarded the decisions of other countries on the extent of protection afforded by article 69 as important contributions to the jurisprudence of his own country. The same is true of the judges of the United Kingdom.

75. The German courts have their own guidelines for dealing with equivalents, which have some resemblance to the Protocol questions. In the "quintet" of cases before the Bundesgerichtshof (see, for example, *Kunstoffrohrteil* [2002] GRUR 511 and *Schneidemesser 1* [2003] ENPR 12 309) which concerned questions of whether figures or measurements in a claim allow some degree of approximation (and, if so, what degree), the court expressly said that its approach was similar to that adopted in *Catnic*. But there are differences from the Protocol questions which are lucidly explained by Dr

Peter Meier-Beck (currently a judge of the 10th Senate) in a paper to be published in the International Review of Intellectual Property and Competition Law (IIC). For example, German judges do not ask whether a variant "works in the same way" but whether it solves the problem underlying the invention by means which have the same technical effect. That may be a better way of putting the question because it avoids the ambiguity illustrated by *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 over whether "works in the same way" involves an assumption that it works at all. On the other hand, as is illustrated by the present case, everything will depend upon what you regard as "the problem underlying the invention." It seems to me, however, that the German courts are also approaching the question of equivalents with a view to answering the same ultimate question as that which I have suggested is raised by Article 69, namely what a person skilled in the art would have thought the patentee was using the language of the claim to mean.

The decision of the Court of Appeal

76. I agree with the Court of Appeal on construction for a number of reasons. First, I think that the judge's construction pays no attention to the claims. It does not even use them as "guidelines" but goes straight to Table VI and declares that to be the invention. Secondly, I think that the Court of Appeal was right in saying that Table VI could not have been the invention. Standing alone, it was a "discovery…as such" within the meaning of section 1(2) of the Act: see *Genentech Inc's Patent* [1989] RPC 147, per Purchas LJ at p 204 and per Dillon LJ at p 237. On the other hand, as Whitford J said in the *Genentech* case ([1987] RPC 553, 566):

> "It is trite law that you cannot patent a discovery, but if on the basis of that discovery you can tell people how it can be usefully employed, then a patentable invention may result. This in my view would be the case, even though once you have made the discovery, the way in which it can be usefully employed is obvious enough."

77. In such a case, while it may be true to say, as the Court of Appeal did ([2003] RPC 31, 62) that Table VI lay "at the heart of the invention", it was not the invention. An invention is a practical product or process, not information about the natural world. That seems to me to accord with the social contract between the state and the inventor which underlies patent law. The state gives the inventor a monopoly in return for an immediate disclosure of all the information necessary to enable performance of the invention. That disclosure is not only to enable other people to perform the invention after the patent has expired. If that were all, the inventor might as well be allowed to keep it secret during the life of the patent. It is also to enable anyone to make immediate use of the information for any purpose which does not infringe the claims. The specifications of valid and subsisting patents are an important source of information for further research, as is abundantly shown by a reading of the sources cited in the specification for the patent in suit. Of course a patentee may in some cases be able to frame his claim to a product or process so broadly that in practice

it will be impossible to use the information he has disclosed, even to develop important improvements, in a way which does not infringe. But it cannot be right to give him a monopoly of the use of the information as such.

New technology

78. The effect of the construction for which Amgen contends is that claim 1 should be read as including any DNA sequence, whether exogenous or endogenous, which expresses EPO in consequence of the application to the cell of any form of DNA recombinant technology. It would have been easy to draft such a claim. Whether the specification would have been sufficient to support it, in the sense of enabling expression by any form of DNA recombinant technology, is another matter to which I shall return when I deal with validity. But the person skilled in the art (who must, in my opinion, be assumed to know the basic principles of patentability) might well have thought that the claims were restricted to existing technology because of doubts about sufficiency rather than lack of foresight about possible developments. Amgen would have been well aware in 1983 that recombinant technology was developing rapidly and that artificial homologous recombination had been achieved in bacterial and yeast cells and that its use in mammalian cells was regarded as a desirable goal.

79. Amgen submit that although homologous recombination was a known phenomenon in 1983, its use to achieve "gene activation" was unknown. The method of manufacture by DNA recombinant technology referred to in the claim was the only one known at the priority date. At the time, it was in practice equivalent to a general claim for manufacture by recombinant DNA technology. It should therefore be construed as such. Amgen say that if the claims cannot be construed in terms sufficiently general to include methods unknown at the priority date, the value of a patent would be destroyed as soon as some new technology for achieving the same result was invented.

80. I do not dispute that a claim may, upon its proper construction, cover products or processes which involve the use of technology unknown at the time the claim was drafted. The question is whether the person skilled in the art would understand the description in a way which was sufficiently general to include the new technology. There is no difficulty in principle about construing general terms to include embodiments which were unknown at the time the document was written. One frequently does that in construing legislation, for example, by construing "carriage" in a 19th century statute to include a motor car. In such cases it is particularly important not to be too literal. It may be clear from the language, context and background that the patentee intended to refer in general terms to, for example, every way of achieving a certain result, even though he has used language which is in some respects inappropriate in relation to a new way of achieving that result: compare *Regina (Quintavalle) v Secretary of State for Health* [2003] 2 AC 687. In the present case, however, I agree with the Court of Appeal (and with the judge, before he came to apply the Protocol questions) that the man skilled in the art would not have understood the claim as sufficiently general to include gene activation. He would have understood it to be limited to the

expression of an exogenous DNA sequence which coded for EPO.

81. The argument over whether the claim can include the new technology is linked to a dispute over the meaning of the second Protocol question. When one asks whether it would have been obvious to the person skilled in the art that the variant worked in the same way as the invention, does one assume that it works? Otherwise, in the case of a technology which was unknown at the priority date, the person skilled in the art would probably say that it was by no means obvious that it would work in the same way because it was not obvious that it would work at all.

82. Some might say, in answer to this question, that it depends on the nature of the invention. For example, in *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 the alleged invention was a second medical use for the known drug rapamycin, which was found to have an immuno-suppressive effect. The question was whether a claim to rapamycin should be construed as including derivatives of rapamycin. The evidence was that the person skilled in the art would be unable to say without experimentation that any particular derivative would have an immuno-suppressive effect. In applying the second Protocol question, it would have been absurd to ask whether, assuming that a derivative "worked" in the sense of having an immuno-suppressive effect, it worked "in the same way". That would really be to beg the question. Neither the product nor the process was new: the whole point of the invention was the newly discovered immuno-suppressive effect.

83. On the other hand, in *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181 the invention was based upon the discovery that an arcuate rod with slits, when rotated at high speed, would take the hair off the skin by means of the opening and closing of the slits. The claim was to a rod in the form of an "helical spring" but the alleged infringer had found that an arcuate rod of vulcanised rubber with slits would do just as well. In answering the second Protocol question, I said that it did not matter that it would not have been obvious to the person skilled in the art to substitute a rubber rod. The question was whether such a rod would work in the same way as an helical spring. I went on, however, to say (in answer to the third question) that "helical spring" could not be generalised to mean any arcuate rod with slits. It meant an helical spring.

84. So perhaps a better answer to the dispute over the second Protocol question is that new technology is another situation in which the Protocol questions may be unhelpful. On the other hand, if the claim can properly be construed in a way which is sufficiently general to include the new technology, the Protocol questions tend to answer themselves.

85. For these reasons I would hold that TKT did not infringe any of the claims and dismiss Amgen's appeal.

Novelty

86. TKT appeals against the rejection by both the judge and the Court of Appeal of its challenge to claim 26 on the ground of anticipation. This raises a point of principle about what counts as a new product.

87. Section 1(1)(a) of the Act says that a patent may be granted only for an invention which is new and section 2(1) says that an invention shall be taken to be new if it does not form part of the state of the art. The Act assumes that any invention will be either a product or a process (see the definition of infringement in section 60.) Claim 26 is to a product, namely a polypeptide which is the expression in a host cell of a DNA sequence in accordance with claim 1. Such a product is EPO and the question is whether it is new or the same as the EPO which was already part of the state of the art, namely the uEPO which Miyake and others had purified from urine.

88. The practice in the United Kingdom under the Patents Act 1949 and earlier was to treat the fact that a product was made by a new process as sufficient to distinguish it from an identical product which was already part of the state of the art. This was not particularly logical, because the history of how a product was made is not an attribute which it carries around and makes it something new. It was still the same product, even if made in a different way. But the English practice had practical advantages when the extent of protection conferred by a patent was undefined (as it was until 1977) and it was assumed that a process claim could be infringed only by using that process in the United Kingdom. A product-by-process claim had the advantage of enabling the inventor of a new process to pursue not only the manufacturer who infringed his claim to the process but also, by virtue of the separate "product-by-process" claim, anyone who dealt in a product which had been made by that process. That was particularly useful in the case of the importation of a product made by someone outside the jurisdiction by a process which would have infringed the process claim if it had been made in this country.

89. The EPC, however, contains a provision which allows a patentee to rely directly on his process claim to allege infringement of a product made (whether within the jurisdiction or abroad) by that process. This is article 64(2) (given effect in United Kingdom domestic law by section 60(1)(c) of the Act):

> "If the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process."

90. This provision largely removes the practical argument for allowing product-by-process claims. The European Patent Office has therefore been able to accept the logical argument that a new process is not enough to make the product new. It will not ordinarily accept a "product-by-process" claim. A patentee who wishes to complain of dealings in a product made by his patented process must rely on his process claim and article 64(2). The principle is clearly stated by the Technical Board of Appeal in *International Flavors & Fragrances Inc* [1984] OJ EPO 309, in which the United

Kingdom was singled out as the only Member State of the EPC which accepted product-by-process claims.

91. The only case in which the EPO will accept a claim to a product defined in terms of its process of manufacture is when the product is new in the sense of being different from any existing product in the state of the art but the difference cannot be described in chemical or physical terms. As the Board said in *International Flavors* (at paragraph 8):

> "This may well be the only way to define certain natural products or macromolecular materials of unidentified or complex composition which have not yet been defined structurally."

92. When the application for the patent in suit was made to the EPO, both claims 19 and 26 were product claims in which the product was described wholly or partly in terms of the way it was made. In the case of claim 19, it was a claim to EPO which was (a) in the form of Table VI ("or any allelic variant or derivative thereof") and (b) "the product of … expression of an exogenous DNA sequence". The Technical Board found on the evidence that EPO which complied with these descriptions would not necessarily be different from uEPO and therefore rejected the claim. Amgen were therefore put to finding some distinction between the patented EPO and uEPO. They amended the claim by adding the words "and which has higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources." I shall come back to the sufficiency of such a claim but there is no doubt that the product would, by definition, be different from uEPO.

93. In the case of claim 26, the EPO was defined as the product of the expression, in a eucaryotic host of a DNA sequence according to claim 1. This is verbally different from the definition in claim 19, which applies to the expression of *any* exogenous DNA sequence, although whether this makes any practical difference is another matter. The Technical Board found on the evidence that expression in a eucaryotic host ?

> "will ensure glycosylation of the product, thus distinguishing it from the prior art."

94. The Board went on to say:

> "The Board is on the evidence prepared to presume that the limitation to the polypeptide being a product makeable using the DNA of Claim 1 is a technical feature which ensures that it has a glycosylation pattern different from the known uEPO."

95. I must confess to being a little puzzled by these findings. It is unclear to me whether the technical feature which ensured novelty was the use of a eucaryotic host cell (as the first quotation above suggests) or whether it was the use of DNA according to claim 1 (as the second quotation suggests). It is true that glycosylation occurs only in eucaryotic cells, but that is no distinction from the prior art because human cells are eucaryotic. Likewise,

the DNA of Claim 1 was alleged to be the human EPO gene as sequenced by Dr Lin. Nor can I quite understand why the Board arrived at a different conclusion in respect of the facts relevant to claim 19. But for present purposes none of this matters: the decision of the Board on claim 26 was based upon a finding of fact that it was necessarily different from uEPO.

96. Neuberger J, on the other hand, found as a fact that there was no difference between uEPO and EPO made according to claim 26. He drew no distinction between EPO made in accordance with claim 19 and EPO made in accordance with claim 26, calling them both recombinant EPO ("rEPO"). He found (at paragraphs 545 to 557) that there was no necessary distinction between rEPO and uEPO. It seems clear that if the European Patent Office had made similar findings of fact, it would have rejected claim 26. So TKT say that Neuberger J ought to have held it had been anticipated.

97. Both the judge and the Court of Appeal rejected this argument as a matter of law, and for similar reasons. In the Court of Appeal, Aldous LJ said:

> "The [Technical] Board [of the EPO] accepted that it is permissible to have a claim to a product defined in terms of a process of manufacture, but state that such claims should only be granted in cases when the product cannot be satisfactorily defined by reference to its composition, structure or other testable parameter. That is a rule of practice which is not the concern of the national courts."

98. That is, I must respectfully say, an incomplete statement of the position of the Board. The first requirement is that the product must be new and that a difference in the method of manufacturing an identical product does not make it new. It is only if the product is different but the difference cannot in practice be satisfactorily defined by reference to its composition etc that a definition by process of manufacture is allowed. The latter may be a rule of practice but the proposition that an identical product made by a new process does not count as new is in my opinion a proposition of law. It cannot be new in law but not new for the purposes of the practice of the Office.

99. Aldous LJ then went on to say "it seems that the Office concluded that claim 26 fell within the type of case where the product could not be satisfactorily defined by its features." That is true, but again incomplete. The important point is that the Office found that rEPO according to claim 26 was a new product because its glycosolation pattern would necessarily be different from that of uEPO. Once this finding of fact was removed, there was no basis for allowing claim 26.

100. Aldous LJ also relied upon article 64(2) as being consistent with a product-by-process claim. But in my opinion it leads to exactly the opposite conclusion and the Technical Board in *International Flavors* so held. The point of article 64(2) is to extend the protection afforded by a process claim to a product directly made by that process and to make it unnecessary to claim the product defined by reference to the process.

101. I think it is important that the United Kingdom should apply the same law as the EPO and the other Member States when deciding what counts as new for the purposes of the EPC: compare *Merrell Dow Pharmaceuticals Inc v H.N. Norton & Co Ltd* [1996] RPC 76, 82. It is true that this means a change in a practice which has existed for many years. But the difference is unlikely to be of great practical importance because a patentee can rely instead on the process claim and article 64(2). It would be most unfortunate if we were to uphold the validity of a patent which would on identical facts have been revoked in opposition proceedings in the EPO. I would therefore allow this part of the appeal and declare claim 26 invalid on the ground of anticipation.

Sufficiency

102. TKT appeal against the Court of Appeal's rejection of their submissions that the specification is, on various grounds, insufficient to support claims 19 and 26. The law on this point is contained in section 72(1)(c) of the Act. A patent may be revoked if the specification does not disclose the invention "clearly enough and completely enough for it to be performed by a person skilled in the art." That means that the disclosure must enable the invention to be performed to the full extent of the monopoly claimed: see *Biogen Inc v Medeva plc* [1997] RPC 1,48.

103. Whether the specification is sufficient or not is highly sensitive to the nature of the invention. The first step is to identify the invention and decide what it claims to enable the skilled man to do. Then one can ask whether the specification enables him to do it. For example, in *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 the patentee claimed that the known drug rapamycin and any of its derivatives could be put to a new use. But the claim for such use of all derivatives was not enabled because only some derivatives could be so used and the specification did not enable the skilled man to identify which they were. The answer may well have been different if the claim was to a new process for making rapamycin and its derivatives or if rapamycin and its derivatives had been new products.

104. It seems to me that a good deal of the argument in this case about sufficiency, like the argument about infringement, really turns on a dispute over exactly what the invention is: whether it is the discovery of the DNA sequence which codes for EPO, or a way of making EPO, or a new artificial form of EPO. And the confusion is compounded by the fact that claims 19 and 26 are both in essence product-by-process claims, even though, in the case of claim 19, the product is distinguished from prior art by an artificial condition about molecular weight. All this creates ambiguity about the nature of the invention. But in order to decide whether the invention has been fully enabled, you first have to decide what the invention is.

105. The complaints of insufficiency are four. First, if (contrary to the view I have expressed on infringement) the claims cover EPO made by any form of recombinant DNA technology, it is said that they are insufficient

because the specification does not enable TKT's technology. I shall call this the "breadth of claim objection". It is a classic patent law squeeze.

106. Secondly, TKT submit that even if the claims are confined to EPO made by the expression of exogenous DNA in a host cell, they enable high-level expression only in CHO cells, which have the genetic mutation allowing Amgen's method of amplification. The specification is insufficient to enable high-level expression in any other cell variety. I shall call this the "cell variety objection".

107. Thirdly, the claims are not only to EPO but to all analogues which behave like EPO in promoting the manufacture of red blood cells. The specification is alleged to be insufficient because it does not enable one to predict which analogues will behave like EPO: (the "analogues objection").

108. Fourthly, the test for distinguishing EPO falling within claim 19 from uEPO (molecular weight) is in practice incapable of application. I shall call this the "molecular weight objection".

109. Before considering any of the four objections, it is, as I indicated earlier, necessary to decide the nature of the invention which the specification had to enable. In my opinion, it was a way of making EPO. For the reasons which I gave when discussing infringement, it was not and could not be the DNA sequence. It could only be a way (however broadly expressed) of making EPO by the use of that information. It could not be EPO itself because that was not new. Nor was it the discovery that a product had a useful quality. The useful qualities of EPO were well known. Even in the case of claims 19 and 26, although they are nominally product claims, the essence of the invention lies in the process. If one keeps in mind that the invention is a way of making EPO, a good deal of the difficulty about sufficiency resolves itself.

Breadth of claims

110. If your Lordships agree with my view on the construction of the claims, they do not cover the TKT process and the specification need not enable it. So your Lordships need not decide whether the specification would have been sufficient if the patent had claimed every method of making EPO by recombinant DNA technology. The judge, for whom the breadth of claims question did arise, said that the TKT process was enabled by the disclosure in Table VI because it could not have been operated without the DNA sequence information. Table VI was, he said, a principle capable of general application. He cited in support the decisions of the Netherlands Court of Appeal in *Kirin Amgen c.s./Boehringer Mannheim c.s.* (27 January 2000) and the Federal Court of Australia in *Genetics Institute Inc v Kirin-Amgen Inc (No 3)* (unreported, 25 June 1998). The Court of Appeal, for whom the question did not arise, was inclined to agree with the judge. Aldous LJ said (at [2003] RPC 31, 64):

> "The law contemplates that patents will not lack sufficiency even

> though the claims cover inventive improvements. If the law was otherwise there would be no room for patents which disclosed a principle of general application unless the specification described how to carry out later inventions using the principle."

111. As the question does not arise for your Lordships either, I do not propose to express a concluded view. But the judge's view was plainly influenced by his opinion that Table VI could itself be the invention. He regarded Table VI as disclosing a "principle capable of general application" and applied a passage from my speech in the *Biogen* case ([1997] RPC 1 at pp. 48-49):

> "If the invention discloses a principle capable of general application, the claims may be in correspondingly general terms … [I]f the patentee … has disclosed a beneficial property which is common to [a class of products] he will be entitled to a patent for all products of that class (assuming them to be new) even though he has not himself made more than one or two of them."

112. This gave rise to a good deal of argument about what amounted to a "principle of general application". In my opinion there is nothing difficult or mysterious about it. It simply means an element of the claim which is stated in general terms. Such a claim is sufficiently enabled if one can reasonably expect the invention to work with anything which falls within the general term. For example, in *Genentech I/Polypeptide expression (T 292/85)* [1989] OJ EPO 275, the patentee claimed in general terms a plasmid suitable for transforming a bacterial host which included an expression control sequence to enable the expression of exogenous DNA as a recoverable polypeptide. The patentee had obviously not tried the invention on every plasmid, every bacterial host or every sequence of exogenous DNA. But the Technical Board of Appeal found that the invention was fully enabled because it could reasonably be expected to work with any of them.

113. This is an example of an invention of striking breadth and originality. But the notion of a "principle of general application" applies to any element of the claim, however humble, which is stated in general terms. A reference to a requirement of "connecting means" is enabled if the invention can reasonably be expected to work with any means of connection. The patentee does not have to have experimented with all of them.

114. In my opinion the facts did not support the application of this principle. Assuming the claims can be read, as the judge thought, to include any way of making EPO by recombinant DNA technology, the specification does not disclose a way of making it in sufficiently general terms to include the TKT process. It discloses only how to make EPO by introducing exogenous DNA coding for EPO into a host cell. The TKT method is not a version of this process which, although untried, could reasonably be expected to work just as well. It is different.

115. The distinction is well illustrated by the Dutch and Australian cases

upon which the judge relied. The issue in the Dutch appeal was whether the invention enabled the use of all forms of exogenous DNA, including cDNA and synthetic DNA. I agree that it did. But that is because cDNA and synthetic DNA were both forms of exogenous DNA. The specification enabled the use of exogenous DNA in general terms and there was no reason for the skilled man to think that, if cDNA or synthetic DNA were obtainable, they would not work equally well. The Australian case was likewise concerned with whether the invention enabled the use of cDNA.

116. The judge appears to have considered that an invention was enabled by a disclosure if it could not be worked without that disclosure. But that is obviously not enough. The disclosure in the specification must be not merely necessary; it must be sufficient.

117. As for the point made by the Court of Appeal, it is of course correct so far as it goes. The choice of a particular form of an integer falling within the terms of the claim may improve the way the invention works and be in itself an inventive step. The specification is not insufficient merely because it does not enable the person skilled in the art to make such an invention. The use of the improvement is still a way of working the original invention. But TKT does not rely upon the fact that the use by TKT of an endogenous EPO gene was inventive. Their objection is that it is not a way of making EPO which is disclosed, even in the most general terms, by the specification. As the point does not arise, I do not propose to express a concluded view. But, unlike the Court of Appeal, I think that the breadth of claim objection may well have been a good one.

Cell varieties

118. By contrast, I entirely agree with the Court of Appeal that the specification enabled the use of any cell for the expression of exogenous DNA. It is true that Amgen were only able to secure high-level expression in CHO cells. But the invention did not promise high-level expression and the discovery of another cell which enabled high-level expression would have been exactly the kind of improvement which the Court of Appeal said did not have to be enabled by the specification. The use of such a cell is a way of making EPO disclosed by the invention.

Analogues

119. In considering analogues, it is important to bear in mind that the invention did not consist in the discovery that EPO and some of its analogues promoted the formation of red blood cells. That was well known. The case is therefore different from *American Home Products Corporation v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 in which the invention lay in the discovery that a known product (and possibly some of its analogues) had an immuno-suppressive effect. But the substance of this invention is a way of making EPO and its analogues. If the claim were to a process for making EPO and EPO-like analogues, it could be sufficiently enabled if the person skilled in the art could make analogues, at any rate if

he could, without undue experimentation, decide whether any given analogue had the necessary EPO-like qualities or not. The difficulty is that whatever may be the substance of the invention, Amgen have chosen to claim the product made by their invention and to define it by reference to its having EPO-like qualities. That difficulty would have been avoided if Amgen had relied upon a process claim and article 64(2). No doubt the reason why they did not do so was that, if they had relied upon the process claim (27), it would have been even clearer that TKT were not using the invention:

> "A process for production of [EPO], which process is characterised by culturing under suitable nutrient conditions a … host cell transformed or transfected with a DNA sequence according to … claim 1 in a manner allowing the host cell to express said [EPO]"

120. In *Amgen Inc v Chugai Pharmaceutical Co. Ltd* 18 USPQ2nd 1016 (1991) the Federal Circuit Court of Appeals held that the claim to analogues was bad and I see the force of the reasoning which led them to that conclusion. As I consider that claims 19 and 26 are both invalid for other reasons, I prefer to express no concluded view on the analogues question.

Molecular weight

121. Claim 19 distinguishes the product falling within the claim on the ground that it has a "higher molecular weight by SDS-PAGE from erythropoietin isolated from urinary sources". SDS-PAGE is a well known method of ascertaining the apparent molecular weight of a protein which is fully described in the judgments below. There is no problem about applying the SDS-PAGE test to two proteins and deciding that one has a higher apparent molecular weight than the other. The difficulty lies in identifying the uEPO to test against the rEPO made according to the process specified in claim 19. The judge heard days of evidence of experiments to determine the molecular weights of various kinds of uEPO. There were variations which might have been attributable to the source of the urine and the method of purification or might have been purely random. The claim, which spoke of "erythropoietin isolated from urinary sources" appeared to be indifferent to source or method of purification. The judge summed up his findings on the experiments at paragraph 479:

> "First, some rEPOs have a higher apparent molecular weight by SDS-PAGE than some uEPOs; secondly, some rEPOs have the same apparent molecular weight as some uEPOs; thirdly, no rEPOs have a lower apparent molecular weight than any uEPOs."

122. In addition, it appeared from a scientific paper in evidence that rEPO expressed in insect cells (which *prima facie* came within claim 19) probably had a lower molecular weight than any uEPO.

123. The judge concluded from this evidence that claim 19 was

incapable of being infringed:

> "It appears to me that the variations in apparent molecular weight between different batches of urinary EPO, coupled with the fact that it is clear that many recombinant EPOs do not satisfy the test, would put the skilled addressee seeking to discover whether his product was within claim 19, and seeking to discover this in a reasonable way, in an unsatisfactory, indeed, an impossible position."

124. The claim appeared to assume that all uEPOs had effectively the same molecular weight, irrespective of source and method of isolation. This had been shown not to be the case. So which uEPO did the claim require to be used for the test? Simply to use the first uEPO which came to hand would turn the claim into a lottery. On the other hand, it would be burdensome to have to work one's way through several specimens of uEPO (which were, as I mentioned at the beginning of my speech, extremely hard to come by) and even then the result would be inconclusive because *non constat* that some untried specimen did not have a different molecular weight.

125. The judge decided that the lack of clarity made the specification insufficient. It did not merely throw up the possibility of doubtful cases but made it impossible to determine in *any* case whether the product fell within the claim. The invention was not disclosed "clearly enough and completely enough for it to be performed by a person skilled in the art": section 72(1)(c).

126. The Court of Appeal disagreed. They said that it was sufficient that some uEPO could be tested against eEPO by SDS-PAGE. The fact that it did not specify which uEPO and that choosing one uEPO would bring the product within the claim and another would not was "lack of clarity dressed up to look like insufficiency." For my part, I do not think that can be right. If the claim says that you must use an acid, and there is nothing in the specification or context to tell you which acid, and the invention will work with some acids but not with others but finding out which ones work will need extensive experiments, then that in my opinion is not merely lack of clarity; it is insufficiency. The lack of clarity does not merely create a fuzzy boundary between that which will work and that which will not. It makes it impossible to work the invention at all until one has found out what ingredient is needed.

127. The Court of Appeal went on to say that even if they were wrong on this point, the claim was sufficiently enabled. They gave the generality of the direction to use uEPO a specificity which they regarded as sufficient with the aid of the following propositions:

> "The onus is upon TKT to establish that the test is insufficient; secondly, that the question of insufficiency has to be judged as of 1984; thirdly, it has to be decided by the court through the eyes of the skilled person; fourthly, the skilled person is deemed to be seeking success rather than failure; fifthly, lawyers can often think

up puzzles at the edge of a claim, but skilled persons are concerned with practicalities not puzzles."

128. The Court of Appeal placed great emphasis upon the fact that the skilled person was taken to be "seeking success", a phrase which is used by Aldous LJ 12 times over six pages. But I am unclear about what in the present context that means. Ordinarily, it is clear enough. The skilled person is taken to be trying to make the invention work. If the skilled person would quickly realise that one method would work and another would fail, the specification is not insufficient because the claim is expressed in terms broad enough to include both methods. That was the point made by Lord Shaw of Dunfermline in the well-known passage cited by the Court of Appeal from his speech in *British Thomson-Houston Company Ltd v Corona Lamp Works Ltd* (1922) 39 RPC 49, 89.

129. In the present case, however, the choice of uEPO has nothing to do with making the invention work. It is simply a criterion against which one tests whether the rEPO falls within the claims. The very concepts of "success" or "failure" seems irrelevant to the choice of uEPO. What counts as "success"? Ex hypothesi the skilled person does not know in advance whether any given uEPO will bring his rEPO within the claim or not. From the point of view of success or failure, one is as good as another. All the skilled man can do is try to guess which uEPO the patentee had in mind and if the specification does not tell him, then it is insufficient.

130. The Court of Appeal then proceeded to re-examine the judge's findings of fact about the conclusions to be drawn from the experiments and scientific papers on the molecular weight of different uEPOs. They excluded some of the samples which he had taken into account on the ground that they would not be considered by a skilled person who was "seeking success". But, for the reasons I have given, that does not appear to me a coherent reason. Others were excluded on the ground that the method of purification would not have been adopted by a skilled man in 1984. The judge was prepared to accept methods of purification which had been published in 1984 (like that of *Miyake et al*, to which I have already referred) and what he called "obvious workshop modifications" of those methods. The Court of Appeal rejected the latter methods on the ground that there was no evidence that the skilled man would have adopted them. But the claims, as I have said, appear to be indifferent as to methods of purification. It is true that the patentee must be taken to have contemplated the kind of method a skilled man would have adopted in 1984 and the patent cannot become insufficient because some entirely different method, consistently producing uEPO with a different molecular weight, is invented afterwards. But the specification refers to a number of methods of purification which were in many respects different from each other. It seems to me unreal to suppose that a skilled person, trying to find out whether his rEPO was within the claims and reading a specification which obviously assumed that the method of purification did not matter, would adhere to the letter of one published method or another and not mix and match.

131. The question of whether the various purification methods were obvious modifications of published 1984 protocols was a matter for the judge who had heard the evidence. In my opinion he was entitled to reach the conclusions which he did and was right in law to conclude that the claim was not sufficiently enabled. I would therefore allow this part of the appeal and restore the judge's conclusion that claim 19 was invalid for insufficiency.

Conclusion

132. The result is that I would allow TKT's appeal and revoke the patent on the ground that claim 19 is insufficient (section 72(1)(c)) and claim 26 is anticipated (section 72(1)(a)). Standing back from the detail, it is clear that Amgen have got themselves into difficulties because, having invented a perfectly good and ground-breaking process for making EPO and its analogues, they were determined to try to patent the protein itself, notwithstanding that, even when isolated, it was not new. Hence the patenting of the two product-by-process claims which have failed, one because the last-minute amendment to distinguish the product from the natural EPO turned out to based upon the false premise that all uEPO had the same molecular weight and the other because the factual basis on which the European Patent Office allowed it turned out to be wrong.

133. I have had the advantage of reading in draft the speech of my noble and learned friend Lord Hope of Craighead and would warmly associate myself with his tribute to Professor Yudkin. His teaching was invaluable to the Committee and must have resulted in a considerable saving in costs for the parties.

LORD HOPE OF CRAIGHEAD

My Lords,

134. I have had the great advantage of reading in draft the speech which has been delivered by my noble and learned friend Lord Hoffmann. I agree with it, and for all the reasons that Lord Hoffmann has given I too would dismiss Amgen's appeal, allow TKT's cross-appeal and make the orders which he has proposed. I wish to associate myself also with the additional points made by my noble and learned friend Lord Walker of Gestingthorpe.

135. Before leaving the case however I should like to pay a particularly warm tribute to the valuable assistance which, with the agreement of the parties and in common with others of your Lordships, I received from Professor Michael D Yudkin, Professor of Biochemistry at Oxford University, in a series of seminars which he gave *in camera* before the appeal was heard to introduce us to the relevant aspects of recombinant DNA technology. The work which Professor Yudkin did by means of these carefully prepared seminars enabled all those involved to concentrate on the issues of law in the appeal without having to spend a good deal of extra time in the course of the hearing on learning about the technology. This had the

result of shortening the length of time that it was necessary to devote to the hearing by several days. It was at Lord Hoffmann's suggestion in the course of a preliminary hearing that this was done, as there was no dispute about the technology. I suggest that it is a course which might usefully be adopted in the future in cases of this kind, where the technology is complex and undisputed and the parties are willing to consent to it.

LORD RODGER OF EARLSFERRY

My Lords,

136. I have had the privilege of considering the speech of my noble and learned friend, Lord Hoffmann, in draft. I agree with it and, for the reasons he gives, I too would dismiss Amgen's appeal and allow TKT's appeal and make the order that he proposes. I also agree with the observations of my noble and learned friends, Lord Hope of Craighead and Lord Walker of Gestingthorpe. There is nothing that I can usefully add.

LORD WALKER OF GESTINGTHORPE

My Lords,

137. I have had the privilege of reading in draft the speech of my noble and learned friend Lord Hoffmann. For the reasons given by Lord Hoffmann I would dismiss Amgen's appeal and allow TKT's cross-appeal.

138. I would add only that I particularly welcome Lord Hoffmann's detailed explanation of the real significance of the *Improver* (or protocol) questions (see *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181, 189; *Wheatley (Davina) v Drillsafe Ltd* [2001] RPC 133, 142) and how they fit in with recent developments in continental patents jurisprudence. There is always a danger that any judicial summary of principle may, precisely because it is concise, practical and repeatedly cited, take on a life of its own, as if it were a statutory text with its own problems of construction to be resolved ("the way the invention works" in the first question is a striking example of this).

139. The fact is that neither *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 nor *Improver* was concerned with anything approaching high-technology science. Lord Hoffmann has demonstrated that in a rapidly-developing, high-technology field the *Improver* questions may have no useful function, and may be a distraction from the one compulsory question set by Article 69 and its protocol.

LORD BROWN OF EATON-UNDER HEYWOOD

My Lords,

140. I have had the great advantage of reading in draft the speech which has been delivered by my noble and learned friend Lord Hoffmann. I agree

with it, and for all the reasons that Lord Hoffmann has given I too would dismiss Amgen's appeal, allow TKT's cross-appeal and make the orders which he has proposed.
