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Kirin-Amgen v Hoechst (TKT)

[2004] UKHL 46

Alan Senior

J.A. KEMP & CO.

Introduction

- Although it is a biotechnology case the opinion of Lord Hoffmann, particularly the first 50 paragraphs or so, is of interest to all patent people for its summary of the development of claim interpretation in the UK and elsewhere in Europe, and its references to US practice
- He reminds us of the original and significant meaning of the Catnic case, and shows us the way in which, in recent years, the Courts may have been wandering away from it and need to have their view refreshed. He also positions us *vis a vis* A69 EPC and the Protocol thereto and speaks briefly of the modern continental approach

Background

- Dispute between Kirin-Amgen Inc (“Amgen”) (a very successful company) and Hoechst Marion Roussel Ltd and Transkaryotic Therapies Inc (“TKT”) concerning EP(UK) 0148605B2, an early EP with earliest priority date late 1983
- Amgen patent 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

Background

- Once Amgen discovered the sequence of the gene which codes for EPO, it was possible to make EPO using methods of recombinant DNA technology which were themselves well known in 1983
- Amgen claimed a method involving the expression of **exogenous** DNA in a host cell, because this was what was known in 1983
- TKT used a new method discovered in the 1990s not available at the date of the patent involving activation of **endogenous** DNA by an exogenous upstream control sequence within the cell

Claims

- Three independent claims:
 - Claim 1, directed to a specific DNA sequence for use in securing the expression of EPO in a **host cell**
 - Claim 19, directed to EPO which is the product of the expression of an **exogenous** DNA sequence
 - Claim 26, a product-by-process claim directed to EPO which is the product of the expression in a **host cell** of a DNA sequence according to claim 1, i.e. definitely doing it the exogenous way

Claims

- Only product claims 19 and 26 were alleged to be infringed, because TKT did not make any EPO in the UK by gene activation

Claim 1

“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).”

Claim 19

“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.”

Claim 26

This was the kernel of the case:-

“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.”

Amgen’s case was therefore that the TKT cells were according to claim 1 and therefore their product fell within claim 26.

First Instance – Patents Court

- Claim 19 was incapable of being infringed and was invalid for insufficiency because the molecular weight of EPO would vary depending on the source of the urine and the purification methods used

First Instance – Patents Court

- In the context of the patent as a whole, the literal meaning of the expression “host cell” in claim 26 would be understood as a cell which is host to **exogenous** DNA, so there was no infringement of claim 26 on a literal construction
- However, it was necessary to apply purposive construction using the “Protocol questions” to see whether TKT’s variant using **endogenous** DNA was nevertheless within the scope of claim 26

First Instance – Patents Court

- Why did the Judge take that step?
- Because that is actually what the Courts have been doing for some time, wrongly they are now told, i.e.
 - (i) to check whether literal infringement occurs
 - (ii) if not, to ask whether the “variant” is within the claim under the Protocol questions
- We digress to look at this under the heading “purposive construction”

Purposive Construction - *Catnic*

- Lord Diplock introduced purposive construction to the patent world in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 marking a change of approach from the more “literal” interpretation of patent claims for which the English Courts were known (and feared)
- This was taken to be a way of working out whether a feature that could be interpreted as a “variant” from the literal wording of the claims really falls within the scope of the claims on a proper interpretation

Purposive Construction - *Catnic*

- The “literal” interpretation had not up to then completely closed the door on variants, i.e. the “literal” and other meanings both appeared to exist up to then, e.g.
 - *Rodi and Weinenberger AG v Henry Showell Ltd* [1969] RPC 367 (watch strap)
 - *C van der Lely NV v Bamfords Ltd* [1963] RPC 61 (hay rake)
- But generally the view was that the patentee must have meant what he said, although we may not know why, and he was usually stuck with it, and indeed the patentee narrowly lost in those House of Lords cases. (1-4 hay rake, 2-3 watch strap)

Purposive Construction - *Catnic*

- *Catnic* abandoned literalism (i.e. abandoned the situation of “literal” and other meanings). This is the thrust of it:
 - “Both parties to this appeal have tended to treat ‘textual infringement’ (*i.e. literal*) 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.” (*Amgen* para 42, quoting Lord Diplock in *Catnic*)

Purposive Construction - *Catnic*

- 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

Purposive Construction - *Catnic*

He said - expanding at some length -

“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.” (*Amgen* para 50, quoting *Catnic*)

Purposive Construction - *Catnic*

and further

“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 ...

Purposive Construction - *Catnic*

to conclude:

... 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.”

(*Amgen* para 50, quoting *Catnic*)

The Improver/Protocol Questions

- The Courts seemed to have some difficulty in putting the principles of *Catnic* into practice, (a bit of a free for all developed) until in *Improver Corporation v Remington Consumer Products Ltd* [1990] FSR 181, Mr Justice Hoffmann (as he then was) analysed *Catnic* as requiring the Court to ask three questions, which became known as the “Improver” questions, or now the “Protocol” questions:

The Improver/Protocol Questions

What this reduces to is this: if there is a feature which falls outside the primary, literal or a contextual meaning it is a variant, and whether the variant is in or out of the claim depends on:-

- (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 (i.e. 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.

Those questions have been asked and answered in a good many cases and have served quite well.

First Instance – Patents Court

- Reverting to *Amgen*, the first instance found no literal infringement, but went on to ask the Protocol questions, as Courts often did.
- Applying the Protocol questions in *Amgen*, the Patents Court considered 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, so the “variant” would have no material effect on the way the invention worked

First Instance – Patents Court

- It would have been obvious to the skilled person that the variant had no material effect
- 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
- The skilled person would not therefore have understood that strict compliance with the primary meaning of “host cell” was an essential requirement of the invention
- **Claim 26 valid and infringed**

Court of Appeal

- The Court of Appeal also applied the Protocol questions, but reached a different conclusion because they identified a different invention and therefore a different “variant”:
- The invention was to them a way of making EPO – the information about the sequence of the gene was necessary to enable the invention to be performed but could not be the invention itself
- It followed from this definition of the invention that a different way of making EPO worked in a different way from that described in the invention
- **Claims 19 and 26 valid but not infringed**
- The fact that these Courts showed different results followed their different ideas as to the invention – that is exactly the problem that had been growing with the Protocol questions.

House of Lords

Lord Hoffmann went back to first principles:

- “There is only one compulsory question, namely that set by Article 69 EPC and its Protocol; which comes down to:
 - 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.” (*Amgen* para 69)

Article 69(1) EPC

“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.”

Pausing here:

Lord Hoffmann says this is particularly significant as regards continental courts, who, before, used claims rather as a springboard or guideline. He emphasises that protection “shall be determined by the terms of the claims”. He believes the German Courts in particular have changed their thinking in the light of this.

Protocol on the Interpretation of Article 69 EPC

“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.”

Protocol on the Interpretation of Article 69 EPC

- The protocol is criticised as vague, but Lord Hoffmann points out that the first sentence is a caricature of the old extreme UK position already abandoned by *Catnic*, and the second sentence reflects the view of the old German position.

House of Lords

- “The *Catnic* principle of construction is ... in my opinion precisely in accordance with the Protocol.” (*Amgen* para 48)
- However, “[t]here 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.” (*Amgen* para 69)

House of Lords

- “ ‘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.” (*Amgen* para 34)

House of Lords

Applying this, and considering the utility of the Protocol questions:-

- “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 on what you think the invention is. Once you have decided that question, the Protocol questions answer themselves.” (*Amgen* para 66)

House of Lords

- The House of Lords agreed with the Court of Appeal that the invention was a way of making EPO
- The claims covered only the method of recombinant technology that was known in 1983 and that was described in the patent, i.e. the method involving exogenous DNA
- TKT used a different method involving endogenous DNA, so there was **no infringement**

Protocol questions - Difficulties

- The House of Lords noted that the Protocol questions are only guidelines, more useful in some cases than in others
- “The first difficulty about the Protocol questions is to decide what is meant by a ‘primary, literal or acontextual meaning’. The [construction of claim 26 by the judge at first instance] could not possibly be described as acontextual.” (*Amgen* para 63)
- “No one has ever made an acontextual statement.” (*Amgen* para 64)

Protocol questions - Difficulties

- There may be some use however in the questions
- “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...*” (where the term “vertically extruding” was at issue) (*Amgen* para 65)

i.e. the Protocol questions are not dead, but of only limited future use

New technology

- Some comments on the new technology situation faced here and the scope of the claim
- According to the House of Lords, it would have been easy to draft claim 1 in broader terms, including any DNA sequence, whether exogenous or endogenous, which expresses EPO in consequence of the application to the cell of any form of recombinant technology (*Amgen* para 78)
- The skilled person 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* para 78)

Conclusions

- It is necessary to look at what the words of a claim *mean*, rather than what they *say*
- The Protocol questions may not always be helpful and should be viewed as a guide, rather than a legal rule
- The Protocol questions may still be useful in determining the scope of claims which include figures or measurements which allow for some degree of approximation, but are less likely to be helpful in other cases

Conclusions

- In the *Amgen* case, it was wrong to construe the term “host cell” in the context of the patent, and then to apply the Protocol questions to extend Amgen’s monopoly beyond the subject matter defined in the claim
- The correct approach was to decide what the skilled person would understand by “host cell” and to determine the question of infringement solely on that basis

Conclusions

- In future one question only will arise and we will not hear much more of the Improved/Protocol questions, not least because Lord Justice Jacob, in the Court of Appeal, dislikes them so much.
- Thus we have probably heard the last of such terms as
 - “an inessential integer”
 - “pith and marrow”
 - “colourable evasion”
 - “benevolent construction”
 - “mechanical equivalents”
 - “ordinary and plain meaning”
 - “textual infringement”
 - “the plain words of the claim”
 - “what is not claimed is disclaimed”

Additional Conclusions

- File wrappers will not come into it:
“why should the meaning change depending on whether the file is considered: they are of limited assistance and life is too short (paraphrase Lord Hoffmann)
- We also have no doctrine of equivalents “the doctrine is one of despair-- once you start you never know when to stop – (paraphrase Lord Hoffmann)
- Does this simplify matters? Yes, there is one question not many. We rely more on the gut feeling. You are less likely to see a claim broadened we think
- Will it be simpler? Lord Justice Jacob in Technip also identified the single question but then identified principles (a) to (k) (which were approved by the House of Lords) to assist in answering the single question which the Courts are now told to address

Product-by-process claims

- Claim 26 was found infringed by the House of Lords. With more shock they also found it invalid. The EPO claimed, regardless of how it was made, was not different from the natural version they said
- The House of Lords endorsed the practice of the European Patent Office, under which the use of a new process is not sufficient to confer novelty on a product, thus overturning the previous practice in the UK (*Amgen* paras 86-101)
- The process features in claim 26 could not distinguish the claimed product from urinary EPO available before the priority date, so the claimed product lacked novelty

Product-by-process claims

- This has left people puzzled. It is of course axiomatic for infringement and validity that claims should have the same scope
- However, the House of Lords considered that the process features were limiting when judging infringement, such that TKT did not infringe claim 26
- Different scope when considering validity and infringement?
- This debate has not got far yet. Alignment with the European Patent Office is a stated aim but many people are not particularly happy with that. This is the next area for discussion

Sufficiency

- Lord Hoffmann stated in an earlier case that, if the invention discloses a principle capable of general application, the claims may be in correspondingly general terms (*Biogen v Medeva* [1997] RPC 1)
- In *Amgen*, he commented further on what is meant by a “principle of general application”:

Sufficiency

- “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.” (*Amgen* para 112)

Sufficiency

- If Amgen's claims had been read as including any way of making EPO by recombinant DNA technology, they would have been insufficient because the specification did not disclose a way of making it in sufficiently general terms to include TKT's method (*Amgen* para 114)
- However, this objection did not arise because the claims were construed as including only ways of making EPO by Amgen's method using exogenous DNA

Sufficiency

- On the facts of the case, the House of Lords held that claim 19 was insufficient because of the requirement that the polypeptide product has a higher molecular weight than urinary EPO
- In view of the variable molecular weight of urinary EPO, the skilled person could not know whether a given product fell within the claim or not

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