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### House of Lords Rules on Sufficiency and Claim Construction in Biotech Case

On 21 October 2004, the Appellate Committee of the UK House of Lords – the UK's highest court of appeal – decided a case of major importance in the field of biotech and pharmaceutical patenting, **Kirin-Amgen Inc and others v Hoechst Marion Roussel Limited and others**.

The patent related to the production of erythropoietin ("EPO") by recombinant DNA technology. The key claims were to (a) a DNA sequence coding for at least a functional part of the EPO molecule and being for use in securing expression thereof in a host (Claim 1), (b) a recombinant polypeptide having at least part of the structural conformation of human or monkey EPO and produced by expression of an exogenous DNA sequence (Claim 19), and (c) a recombinant polypeptide produced by one of a number of specific DNA sequences (Claim 26). It was envisaged that the exogenous DNA would be inserted in a non-human host and the expressed EPO would be harvested and administered to a human requiring it.

The defendants had developed a process for making EPO by activation of a natural ("endogenous") EPO gene that ordinarily would not express EPO but could be made to do so by inserting an upstream control sequence at a specific location of the genome in relation to the natural EPO gene. Therefore, "exogenous" DNA was used, but not exogenous DNA coding for EPO. The defendants proposed to import the resultant "gene-activated" EPO (GA-EPO), which is chemically the same as the patentee's product.

Infringement of Claims 19 and 26 by importation of GA-EPO was asserted by Amgen. In the Court of Appeal, Amgen had lost on infringement but the patent had been held valid. Both sides appealed to the House of Lords, Amgen on infringement and the defendants on validity. The House of Lords dismissed Amgen's appeal, allowed the defendants' cross-appeal on validity, and found that Claims 19 and 26 were invalid and/or not infringed.

The following interesting questions were addressed in the Kirin-Amgen decision:

- **What is the proper approach to construction of patent claims in the UK (Question 1)**
- **If an alleged infringing product/process required significant further work to achieve, which was not disclosed in the patent, to what extent can the patent thereby be challenged by the alleged infringer on the ground of insufficiency? (Question 2)**
- **If a claim defines a parameter of a product in relation to a prior art reference material, and the parameter of the reference material is indefinite, can the claim be challenged on the ground of insufficiency even though "lack of clarity" is not a formal ground of invalidity? (Question 3)**
- **Given that "product-by-process" claims are currently interpreted differently as between the European Patent Office and the UK courts and Patent Office, should that difference be removed for the sake of uniformity? (Question 4)**

The court gave the following guidance:

#### Question 1

The court held that construction of patent claims in the United Kingdom is governed by the Protocol on the Interpretation of Article 69 of the European Patent Convention, which essentially requires that the courts balance fair protection for the patentee with a reasonable degree of certainty for third parties (*Opinion of Lord Hoffmann, Paragraph 26*).

The court indicated that the previous general approach of trying to establish the purposive construction of the claims – i.e. what the claims define when the purpose of each element is considered – accords with the balancing task of the court (*Paragraph 48*). However, the three so-called "protocol questions", which the courts had developed in mechanical cases order to try to structure the analysis, should not be applied if they obscure, rather than assist, the task (*Paragraph 52*). The court indicated that this might often be the case where the issue was not whether strict compliance with certain figures, measurements or angles was intended, but rather whether the reader would understand the underlying invention to be operating at a particular level of generality (*Paragraphs 65 and 66*). The court explicitly distinguished the UK doctrine of purposive construction from the US doctrine where "equivalents" outside the scope of the claims can be considered as infringements (*Paragraph 42*).

This approach led the court to find the defendant's product did not infringe. The DNA referred to in the claims was exogenous DNA coding for EPO, and such DNA played no part in the defendant's activities.

#### Question 2

The court's comments on this question were, strictly speaking, *obiter*, in view of the finding of non-infringement. However, the questions of how far a pharmaceutical or biotech claim can extend from the examples without losing sufficiency, and how far sufficiency, claim interpretation and the description of the invention are linked, are of great practical importance.

As expected, the court confirmed that, in principle, a claim can be construed in such a way as to validly protect an invention even when worked at some future date with technology that was unknown at the time of the patent. This will be the case where the invention involves a principle of general application, in the sense of an element of the claim which is stated in general terms (*Opinion of Lord Hoffmann, Paragraphs 110 to 113*).

However, an insufficiency challenge may be sustainable where a product/process falling within the claim required further development work which was not disclosed in the patent, provided that the reader of the patent would not reasonably have expected such a product/process to work. The court considered that the differences between the defendants' method and the patentee's method "may well" have been enough for an attack of insufficiency to succeed on this basis, if the claims had covered GA-EPO (*Paragraphs 113 to 117*).

### Question 3

The court stated that, in the situation outlined in Question 3, an attack on the ground of insufficiency is available against the claim, even though "lack of clarity" is not an available ground of invalidity of a patent (*Opinion of Lord Hoffmann, Paragraphs 121 to 131*).

### Question 4

Traditional UK practice has been that a process patent may include product-by-process claims, even where the product is not novel. The novelty and inventiveness of such claims where the product itself is not new would derive from the process, not the product. This differs significantly from the position in the European Patent Office and some other Member States, where product-by-process claims are only permitted where the product is new. In those jurisdictions, the novelty and inventiveness of such claims derive from the features of the product (including any features which are the inevitable result of the stated manufacturing process). The court stated that the UK should apply the same law as the European Patent Office and the other Member States. In other words, product-by-process claims should now only be permitted where the product is new (*Opinion of Lord Hoffmann, Paragraph 101*).

### Comments

**The effect of the Kirin-Amgen decision on product-by-process claims is not yet clear. We will keep you informed of developments. It is reasonable to assume, however, that these claims are now at risk of invalidity if they relate to a known product prepared by a new process and the process does not impart any demonstrably new characteristic to the product.**

**The Kirin-Amgen decision reinforces the need for patents in the pharmaceutical and biotech areas to include from the start: good amendment positions to allow asserted claims to be restricted rather tightly onto infringements; representative examples showing workability across the full claimed scope; and a claiming strategy that is founded on a genuinely reasonable and credible extrapolation from the specific examples and uses only clear and reproducible parameters.**

• (<http://www.parliament.the-stationery-office.co.uk/pa/ld200304/ldjudgmt/jd041021/kirin-1.htm>)

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