> *"I believe Article 69 of the EPC does not legitimately allow courts to construe claims using the prior art either to widen them or narrow them. There is normally no reason to suppose the patentee when he set the limits of his monopoly knew of a particular piece of prior art which is therefore irrelevant in deciding what those limits are. Of course the position is different if the prior art is specifically acknowledged in the patent. The purposive construction would lead to a construction of a claim which did not cover that acknowledged prior art; it can hardly have been the inventor's purpose to cover that which he expressly recognises was old".*

27. By parity of reasoning, it is submitted that a purposive construction which would lead to a claim of sufficient scope to cover that which had been held specifically to be unpatentable by reason of the disclosure in the specification would likewise not embody the inventor's purpose. Objectively it cannot have been the inventor's purpose to cover that which was not enabled by his specification.

28. The same applies to subject matter that has been specifically disclaimed by the patentee in the specification. The TBA in *JSR / Block copolymer* (T416/87) [1991] EPOR 25 said:

> *"In the Board's view, if the description on its proper interpretation specifies a feature to be an overriding requirement of the invention, following Article 69(1) EPC and its Protocol the claims may be interpreted as requiring this as an essential feature, even though the wording of the claims when read in isolation does not specifically require such a feature."*

29. What is it then that the notional skilled man has before him when seeking to identify the true meaning of the claim? The specification on its face makes it plain that it is an amended specification by use of the suffix B2 and by the indication of the date of publication and mention of the opposition decision on 23.12.1998.

30. It would be wholly inconsistent with the objective of the Protocol, namely achieving a balance between fair protection for the patentee and reasonable certainty for third parties, for the court not to have regard to the amendments in

seeking to construe the amended document. Jacob J. appears to have accepted this (albeit *obiter*) in *Bristol Myers Squibb v. Baker Norton* [1999] RPC 253 at 274.

31. In conclusion therefore, it is submitted that in reaching a proper interpretation of the claims in circumstances where there has been amendment in the course of opposition, it is proper for the court to have regard to the differences between the amended and unamended specifications in reaching the correct answer on construction following the requirements of the Protocol.

32. Whilst there is no developed doctrine of this nature in the courts of this country, both in the Netherlands and Sweden the courts do permit recourse to matters which have occurred in the course of prosecution and which appear on the public prosecution file in the course of carrying out their obligations under the protocol. In the Netherlands the Supreme Court has considered the matter in *Ciba Geigy v. Ote Optics* (13/1/85, NJ 1995 391) and also in *Dreizler v. Remeha* (13/1/95, RvdW 1995, 26). In Sweden, the matter has been considered by the Stockholm City Court in *Spanak v. Allround-Smide* (6/5/97). Whilst these cases all relate to observations made by the patentee in the course of prosecution, it is submitted that the logic applies with even greater force to amendments offered voluntarily by the patentee in the course of opposition proceedings in order to overcome objections made. It appears that Jacob J. accepted the force of this in the *Bristol Myers Squibb* case.

Construction of claim 1

33. Three questions arise in relation to claim 1:

(i) Does the claim extend to all DNA sequences including a cDNA sequence coding for human EPO?

(ii) Which DNA sequences are covered in feature (b) of the claim by the expression "which hybridizes under stringent conditions"?

(iii) Which DNA sequences are encompassed by feature (c) by reason of the degeneracy of the genetic code?

The second and third of these will be considered below under insufficiency.

34. The first of these questions however raises in stark form the question of construction referred to above. If the B2 specification is considered on its own, the focus of the teaching is human genomic DNA and monkey cDNA. Consistent with this, none of the claims are specifically directed to a human EPO cDNA sequence. By contrast, there are dependent claims that expressly cover monkey EPO cDNA (claim 3) and genomic DNA (claim 5).

35. Reference to the B1 specification [A2/2] and the amendments made thereto in the course of the proceedings before the TBA shows that originally claim 3 was expressly directed to a cDNA sequence either according to claim 1 or claim 2 and claim 2 was limited to a DNA sequence encoding human EPO. As amended claim 3 is limited to a cDNA sequence according to claim 1 which is a monkey species EPO. A copy of the claims with the amendments marked is attached to this skeleton.

36. Nonetheless, apparently, the Amgen parties seek to interpret claim 1 as being wide enough to cover a DNA sequence which is a cDNA sequence encoding human EPO. In the course of the TBA decision, it was expressly held that a claim which covered a human cDNA sequence was not enabled (see §§19-29 of the decision). Accordingly claim 3 was insufficient. To meet this Amgen volunteered a form of amendment which excluded express protection for human cDNA.

37. The unamended specification is available to all and it is submitted that in order to achieve the balance required by the Protocol, the courts in this country must have regard to that document in interpreting the claim. It would make a nonsense of the TBA decision and the voluntary offer by Amgen to exclude human cDNA sequences from the express scope of their protection if they were able thereafter to contend that nonetheless the patent still covered such

sequences by reason of the language in claim 1. Indeed it is clear from reading the patent that the invention relates to human EPO genomic DNA and monkey EPO cDNA – and not to human EPO cDNA. Purposively construed, this is not a patent which extends to human cDNA and by no stretch of the imagination can it be suggested that it was, objectively, the inventor's purpose to cover human cDNA.

38. Accordingly the Roche parties contend that on its true interpretation claim 1 should be interpreted as excluding cDNA sequences encoding human EPO. Such an interpretation gives fair protection to the patentee and also enables third parties to enjoy the certainty which, apparently, was created by the disclaimer to claim 3 and the TBA decision. If the claim is not construed in this way then it is insufficient – see below.

39. For all these reasons it is contended that the claims of this specification should not be interpreted so as to be wide enough to cover a human cDNA sequence.

MERE DISCOVERY

40. Section 1(2) of the 1977 Act provides:

> *"The following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -*
> *(a) a discovery.....*
> *but the foregoing provisions shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such."*

41. The Roche parties contend that, in so far as the 605 patent claims genomic DNA (human or otherwise), this is not in respect of an invention as such a claim is to a discovery as such. This is pleaded at §5 of the P of O [B1/5] and relates to claims 1, 2, 5, 6, and 7 of the 605 patent (in so far as they relate to genomic DNA). In simple terms a genomic DNA sequence, coding for a particular protein, amounts merely to a discovery of something that existed previously in nature.

42. A clear explanation of the difference between an invention that may be granted patent protection and a mere discovery was given by Buckley J. in *Reynolds v. Herbert Smith* 20 RPC 123. Buckley J. stated at page 126 of his judgment:

> *"Discovery adds to the amount of human knowledge, but it does so only by lifting a veil and disclosing something which before had been unseen or dimly seen. Invention also adds to human knowledge, but not merely by disclosing something. Invention necessarily involves also the suggestion of an act to be done, and it must be an act which results in a new product, or a new result, or a new process, or a new combination for producing an old product or an old result."*

43. One of the recent cases that considers the law of mere discovery is *Fujitsu's Application* [1997] RPC 608. Here the Court of Appeal confirmed again that mere discoveries or ideas were not patentable *per se*, but discoveries or ideas which have a technical aspect or make a technical contribution may be patentable. In his judgment Aldous L.J. reviewed *Merrill Lynch's Application* [1989] RPC 561 and *Gale's Application* [1991] RPC 305. He also considered the decision of the TBA in *Vicom* (T208/84) [1987] 2 EPOR 74, in which the TBA stated at §16 of their decision:

> *"Generally speaking, an invention which would be patentable in accordance with conventional patentability criteria should not be excluded from protection by the mere fact that, for its implementation, modern technical means in the form of a computer program are used. Decisive is what technical contribution the invention as defined in the claim when considered as a whole makes to the known art".*

44. At page 614 of *Fujitsu*, Aldous L.J. stated that:

> *"The decision as to what was patentable depended on substance not form..... it is and always has been a principle of patent law that mere discoveries or ideas are not patentable, but those discoveries and ideas which have a technical aspect or make a technical contribution are. Thus the concept that what is needed to make an excluded thing patentable is a technical contribution is not surprising. That was the basis for the decision of the Board in Vicom. It has been accepted by this court and by the EPO and has been applied since 1987. It is a concept at the heart of patent law."*

45. Perhaps the most suitable case to consider with reference to this point is *Genentech's Patent* [1989] RPC 147. Here Genentech had carried out a research project that resulted in identification of the DNA and amino acid sequences of human tissue plasminogen activator (t-PA) and also in the production of vectors incorporating a cDNA insert corresponding to such a sequence. It was held in that case that the determination of the full amino acid and DNA sequences coding for t-PA constituted a discovery. As described by Mustill L.J. at page 269 the t-PA protein (as embodied by its sequence data) was an "*existing fact of nature, newly discovered.*" See also Purchas L.J. at page 227.

46. The Court of Appeal decided that claims 2 and 4 of the Genentech patent, which claimed a monopoly in respect of all pure protein having the amino acid sequence in figure 5 of the patent (this figure comprised the full length nucleotide and derived amino acid sequences of the t-PA protein), were not claims for the practical application of the discovery (that is the sequence data) and so fell foul of section 1(2) of the Act.

47. By applying the same reasoning, claims 1, 2, 5, 6 and 7 of the '605 patent (in so far as they relate to genomic DNA) do not claim anything other than a discovery as such. Although claim 1 of the '605 patent does include the words "A DNA sequence for use in securing expression in a prokaryotic or eukaryotic host cell", the words 'for use in' only mean suitable for or has appropriate features for and do not amount to a practical application of the discovery (that is, the genomic DNA sequence). Nothing has been added to this claim by using these words that converts the mere discovery into an invention. The patentee's invention was a means of obtaining the genomic DNA and not the DNA sequence itself.

48. This reasoning helps to identify that the desiderata of recombinant EPO and sequences for use in the production of recombinant EPO were known. What was not known was the route by which these desiderata could be achieved. This is an important consideration when identifying the technical contribution to the art made by the patent, the identification of which is fundamental to an assessment of sufficiency.

SUFFICIENCY

The law

49. It is not proposed in this skeleton to rehearse the law on insufficiency in detail. This court has recently been concerned with the question of sufficiency within the meaning of section 72(1)(c) of the 1977 Act in *Novo Nordisk v. DSM*.

50. There are essentially two different aspects of insufficiency:

(i) Insufficiency where the specification does purport to disclose a method of putting the invention into effect but does not do so in a sufficiently complete manner. The question then is whether the description is sufficiently complete for the skilled addressee to understand the invention and perform it. The relevant criteria are set out in the judgment of Lloyd L.J. in *Mentor v. Hollister* [1993] RPC 7 at 10.

(ii) Insufficiency relating to the breadth of claim. Even if a patent does disclose one way of performing the invention, if the claim covers other ways as well, the disclosure must be sufficient to enable those other methods to be performed. Here the leading authority is *Biogen v. Medeva* [1997] RPC 1 at 47-53. See also the TBA decision in *Mycogen / Modifying plant cells* (T694/92) [1998] EPOR 114.

These aspects of sufficiency have recently been considered further in *American Home Products v. Novartis (No. 2)* [2000] IP&T 1308 and *Monsanto v. Merck* [2000] RPC 709.

51. The addressee of the patent cannot be called on to exercise invention in putting the patent into practice nor can he be required to carry out "any prolonged research enquiry or experiment" or "to make a prolonged study of matters which present some initial difficulty". In particular, where there are errors or omissions in the specification, the addressee must be able quickly to discover both the

existence of the problem and the way of overcoming it (see the passage from *Valensi v. British Radio Corporation* [1973] RPC 337 cited on page 13 of *Mentor v. Hollister*).

The issues

52. We summarise below the issues which arise on the Roche parties' insufficiency pleading [B1/5]:

(1) Human cDNA - P of O §3(a)

(a) In the patent as granted, claim 3 specifically covered a cDNA sequence encoding human EPO. The TBA held (see §§12-29) that the specification was insufficient in its disclosure in relation to human cDNA so that this claim was invalid.

(b) The Amgen parties apparently contend, notwithstanding this, that claim 1 is sufficiently broad to cover a cDNA sequence encoding human EPO and hence that claims 26 and 27 are infringed by virtue of the Roche parties' use of such a sequence.

(c) For the reasons given above, on the proper construction of claim 1, it does not extend to cover a cDNA sequence encoding human EPO. Insofar as it does, it is insufficient by parity of reasoning with that of the TBA in relation to old claim 3. It is this issue that is raised in §3(a) of the P of O.

(2) Breadth of claim 1 - P of O §3(c).

(a) This plea addresses the breadth and uncertainty introduced into claim 1 by parts (b) and (c).

(b) Part (b) refers to DNA sequences that hybridise under "stringent" conditions (whatever they may be) to the protein coding regions of the DNA sequences in part (a) of the claim or (to undefined) fragments thereof. This is a wide and indeterminate class, the production of which is not enabled across its full width by the disclosure in the patent. A similar point also arises on part (c) which requires simply hybridisation (there is no reference to "stringent" conditions).

(c) Part (c) also raises the not unfamiliar problem of the extent to which it is proper to claim not only sequences which hybridise but also those that would hybridise were it not for the degeneracy of the genetic code. As pleaded in §3(c)(2)(iv) of the P of O, it requires undue effort to identify such sequences and/or, conversely, to know whether any given sequence falls within the claim.

(3) The failure to deposit the EPO gene or a source of it - P of O §3(e).

(a) In the case of the 605 patent, in contradistinction to the 678 patent, no material was deposited in accordance with Rule 28 of the Implementing Regulations. It is well accepted that in some cases it is difficult to describe a biotechnology invention in writing and the deposit of biological material has become an internationally accepted practice for supplementing the written disclosure of a patent application.

(b) This does not necessarily mean that failure to deposit is fatal to the sufficiency of a specification. In this respect §76 of the reasoning of the TBA is accepted. Each case must be decided on its own facts and where there is no deposit, the description may nonetheless be such as to be sufficient. The TBA held that the description in the 605 patent was sufficient in this regard. We contend that this part of the TBA's decision was wrong.

(c) In this skeleton we consider the failure to deposit the EPO gene or a source of it together with the issues raised under point (5) below.

(4) Procaryotic host cells - claims 1 and 27 - P of O §3(f)

This is a small point. The reference to procaryotic expression in claim 19 has rightly been deleted since procaryotic cells do not glycosylate and thus produce EPO which is inactive *in vivo*. The same reference in claims 1 and 27 should be deleted for the same reason. We do not propose to say anything further about this in this skeleton.

(5) Undue burden - claims 19, 26 and 27 - P of O §3(g)

This is a standard insufficiency argument. There has been no deposit and the relevant examples in the specification (7A, 7B and 10) are sufficiently

riddled with errors and omissions to place an undue burden on the skilled man wishing to produce a claimed polypeptide or carry out the claimed process.

The plea has been amplified in the Amended Further Information [B1/12].

(6) Higher molecular weight by SDS-PAGE - P of O §3(h)

This plea, which relates to claim 19 and dependent claims, falls into two parts.

(a) First, there is a general plea which mirrors equivalent pleas in relation to claim 1 (see §3(h)(1)).

(b) Secondly there are specific pleas in §3(h)(2)-(4) which relate particularly to the inadequacy of the description of the urinary EPO to be used for comparative purposes and the manner in which a given polypeptide is to be compared therewith.

(7) *Biogen* insufficiency - P of O §3(i)

(a) The technical contribution of the patent resides in the provision of a process by which recombinant EPO can be prepared by way of a genomic DNA sequence or by way of a monkey cDNA sequence.

(b) To the extent that the claims extend further to cover processes (or products which are prepared by processes) which owe nothing to that contribution, including in particular, processes which are dependent upon the use of a human cDNA sequence, the claims are invalid.

(c) Further, even if it were to be shown that the specification did enable some route to a human cDNA sequence, such enablement would not entitle Amgen to claims covering all possible routes.

53. It should be noted that the Amgen parties have declined to identify the independently valid claims of the 605 patent in the light of the Roche parties' insufficiency attacks (see letter of 30 June 1999 [B1/33]). The Roche parties are of course primarily concerned with the claims which they are alleged to infringe (as set out in that letter). Our focus in this skeleton is therefore primarily directed at claim 19 and at claim 1 (on which claims 26 and 27 are dependent). We do not believe that any of the other claims which the Roche parties are