

CIPA

THE CHARTERED INSTITUTE OF PATENT AGENTS

Staple Inn Buildings,
High Holborn,
London WC1V 7PZ

Telephone: 0171 405 9450
Facsimile: 0171 430 0471

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Commissioner of Patents and Trademarks,
Box 8,
Washington, D.C. 20231
USA

12 November 1998

For the attention of: **Scott A. Chambers, Associate Solicitor**

Dear Commissioner

**Comments on the Interim Guidelines for Examination of Patent Applications
under the 35 USC 112, paragraph 1 "Written description" Requirement**

Copies of these comments are being sent by email, fax and paper post.

The commenting body

These comments are respectfully submitted by the Chartered Institute of Patent Agents, London ("CIPA") through its Biotechnology Committee. The Committee consists of patent attorneys entitled to practice under UK domestic and European Patent Convention law. Its membership is drawn from industrial company patent departments and private practice.

General Remarks

There is a big question in many minds, including ours, about the "written description" requirement: is it really distinct from the requirement for an enabling disclosure?

CIPA agrees with those who think that the decision in *University of California v. Eli Lilly* has not settled this point definitively. Part of the difficulty is that US patent law affecting biotechnology seems to be creating jurisprudence specific to the technology. We instance the decisions *In re Bell* and *In re Deuel*. The legal concept that a product is patentable, simply because its structure (DNA sequence) was unknown, when it was obvious to make, and how to make, the product, is (we think) wrong. It conflicts with well-established law in other fields of art, of anticipation or obviousness by inherency.

Equally, we feel that *University of California v. Eli Lilly* is inadequate to provide a basis for a full restatement of the law in the proposed interim guidelines... The decision may be justified on the facts of the case at that relatively early time in the history of DNA inventions, but it would be wrong to extrapolate the decision to apply in the same way today. Nowadays one would normally expect that DNA encoding a protein of known generalised function, such as insulin, would not differ too much between one animal and another. Thus, providing the DNA sequence for one animal would normally enable appropriate probes or primers or mixtures thereof to be constructed, to enable the isolation of the corresponding DNA of another animal.

We are not aware of any requirement for 'written description' separate from 'enablement' in the laws of other countries, and we doubt that it is consistent with the TRIPs provisions of the World Trade Organisation.

If there have to be guidelines for written description relating to biotechnology inventions, CIPA believes that they should not impose requirements on applicants which are not applied (so far as possible) in other fields. It is right to apply any guidelines to all technologies. However, CIPA believes that the examples given are not fully representative of day-to-day fact situations facing biotechnology patent applicants.

We think that it is important to grant claims of scope appropriate to the enabling disclosure in a patent specification. In particular, broad functional claims lacking defining structure should not readily be granted on the basis of a limited and not easily generalisable disclosure. Conversely, a quite limited specific disclosure is proper basis for a broad claim if it is apparent that it can be generally applied. Boilerplate disclosure and constructive examples are unnecessary in a patent specification, if they are no more than what the expert can provide for himself. Requiring multiple examples to prove possession of a genus will sometimes be appropriate; but to ask for such examples when they are not essential will discriminate against the small inventor with limited resources, and thwart all his efforts. We hope the guidelines will keep these objectives in balance.

It is unclear from the guidelines what "possession" of an invention is. If one has "made" an invention, is one necessarily "in possession" of it - or is there some further criterion, such as actual reduction to practice of an appropriate number of embodiments, to be met?

Specific remarks

In these specific remarks, reference is made to the lettered and numbered paragraphs of the interim guidelines as submitted to the public for comment.

AI It is respectfully questioned whether an important objective of the written description is to "clearly convey the information that an applicant has invented the subject matter which is claimed". This is not clear - does "has invented" mean "has actually reduced to practice" - or something else? We doubt if this *dictum* is really helpful, particularly since an invention cannot be negated by the manner in which it is made. The essential requirement, surely, is to teach the public how to carry out the invention by making an enabling disclosure. The objective which the guidelines quote - "ensuring that patentees adequately describe their inventions in their patent specifications for the benefit of the public" - provides no justification for anything beyond an enabling disclosure. If the

disclosure does not put the public in possession of the invention, there is no proper consideration for grant: the fact that the inventor possessed the invention and could have described it in a repeatable way (had he been more skilful or better advised) is beside the point. Conversely, if the description actually does enable the public to practise the invention, why go behind that and ask whether the inventor has himself already done so?

However that may be, the fundamental legal propositions on which the guidelines are based are not made clear. Is it the Patent Office's position that to claim any new product species, the applicant must actually have made it? We presume not. There are many situations in which if you describe a new product, anyone can see how to make it. Frequently, it is obvious how a product could be made, but unobvious that the person skilled in the art would have the motivation to make it (because he has not appreciated that the product has unexpected properties). This applies for all kinds of invention, mechanical, electrical, chemical and biological. Biological examples are (say) DNA from a known virus which acts as a general cell stimulator and a short peptide which has a therapeutic use in blocking a certain receptor site. If the method of making the product is unobvious, we can understand the case for asking for evidence that the structure has actually been made (though we continue to believe that the right question is whether the specification gives enough information to enable the skilled reader to make it). Is the "predictability of structure", which the Examiner has to determine under the new guidelines, the means by which the Examiner is to decide whether the specification must contain evidence that the product has been made, rather than simply a repeatable written description of how to make it? If this is the intention, we think it could be made clearer.

The guidelines do not make clear precisely what kind of description equates with possession of a claimed species. For example, where it is unobvious how to make the product, it would seem reasonable to require an applicant to quote some property or structural detail of the product or detail of a process of preparing it which he could not reasonably have known unless he had made the product or carried out the process. Yet, the guidelines do not say this in a clear way.

The problem is still more difficult when it comes to showing possession of a generic invention. No-one can make all possible species: at most, only a representative number of species can be required. However, it is important that a single species should be recognised as properly justifying a claim to a genus in the right circumstances: if not, rich applicants will have to do expensive and unnecessary experiments, and poor applicants will be denied the protection their inventions merit.

CIPA is concerned that these guidelines do not deal adequately with the amount of written description required in a very common situation: where there is only one example or embodiment, but from this can reasonably be derived a general technical principle. In such a situation, the inventor should not be required to possess more than the one example or embodiment.

The guidelines do helpfully explain possession in paragraph D by stating (in connection with the mutanase example) that if an applicant is in possession of three species in a well developed field of art so as to reasonably predict sufficient identifying characteristics of the other members of the genus, then he has established possession of the genus. However, this is a long way from dealing with the "one embodiment/general principle" situation. It appears to be the intention that such

applications will always be rejected for lack of written description simply because they disclose only one example or embodiment. CIPA is unhappy with this approach.

AII It is not clear what is meant by "... what applicant has described, i.e. has possession of ...". Can general description contribute to possession? Or is only specific description meant? How are the two distinguishable?

B The examples given are unclear. They seem to imply that "A nucleic acid comprising SEQ ID NO: 1" is subject to a more lenient application of the written description requirement than the narrower claim. "A cDNA comprising SEQ ID NO: 1". This is baffling, as it seems to be encouraging broader claims.

The suggestion that a claim to a cDNA must be accompanied by a written description of promoters, enhancers, coding regions and regulatory elements is of concern. These do not seem good examples, as normally the person in the art would be able to supply these from his own knowledge. Although "what is well known to one skilled in the art need not be disclosed" (paragraph C), the listing of these specific items suggests that examiners will routinely demand a description of them. Biotech patent specifications, frequently very long, will thus become longer. This has already happened in the chemical field, where applicants find it necessary to insert long lists of pharmaceutical carriers and acids for making addition salts. This is not a desirable development.

It is unclear how the guidance in B is intended to affect applicants who have identified new genes as a result of large scale cloning projects.

While the Examiner must look carefully in every case at what the applicant has actually invented, we believe that it will often be misconceived to require significantly more disclosure to support a narrow "gene" claim than for a broader "DNA" claim. It has been suggested that this is to prevent subsequent inventors being pre-empted by an earlier inadequate disclosure. This seems to us unnecessary. Subsequent inventors have two problems: the scope of prior claims, and the disclosure of earlier specifications. Only the latter affects what they can patent: only the former affects what they can exploit commercially. If the later inventor discloses something inventive over the earlier disclosure, he will be able to patent it (whatever the earlier claims say): if not, not. Perhaps a more important question is whether an inventor of a short DNA sequence useful as a probe should be allowed claims that dominate all genes containing the sequence: so far as we can see, the guidelines do not deal directly with this point. Even if this is only a transitional problem, now that sequencing and "gene walking" is so much easier, it should be tackled.

C(1) The sole example is unrealistic. No experienced practitioner would seek to claim a probe consisting of a particular sequence, since it could be evaded by making it longer or shorter. This "safe harbour" is so safe that it contains no water!

C(2) The first example (Golden Mosaic Virus DNA) is unrealistic, again because of "consisting of" language. It would be more useful to discuss the broadest claim available in the light of the fact situation.

In connection with the second example (alginate lyase enzyme), the guidelines suggest that "one skilled in the art would recognise from the characteristics... that applicant was in possession of the claimed material". This seems to conform to the principle set forth above in these comments, that an applicant should quote some property or structural detail of a product which he could not reasonably have known unless he had made the product. If this is to be applied generally, the guidelines should say so.

As will be evident from the general remarks above, CIPA does not agree with the third example under C(2) (insulin). Whether the structure of the second gene can be predicted or not is immaterial if the second gene was clearly obtainable from the first gene (the structure of which was disclosed) by simple experiment. Since in most modern-day situations it will be obtainable by simple experiment, this is a bad example.

D Much of this paragraph is helpful and welcome. However, the reference to various animal species is not clear and would be dealt with better by a specific fact situation. Here, it would probably not be known whether there is extensive variation between species in respect of the claimed subject matter: a judgement would need to be made. We would certainly hope that in many situations it would be possible to claim a genus without having to provide nine specific worked examples of species.

The example of the DF3 enhancer appears reasonable, but shows how unreasonable is the example of "A gene comprising SEQ ID NO:1" (from Section B). In the DF3 case, assuming that a translational (rather than a transcriptional) enhancer is intended, the translation of any heterologous gene is deemed to have been described adequately. It is not apparent why one claim is patentable and the other not. Also, in view of the examples in Section B, it is not clear whether any significance should be ascribed to the difference in the definition of the DNA ("DNA" for the DF3 enhancer example; "gene" for the SEQ ID NO: 1 example).

Conclusion

CIPA questions whether a requirement for written description is truly different from a requirement for enablement. Such a requirement may be contrary to the TRIPs provisions of the World Trade Organisation (Article 27.1).

If guidelines have to be introduced to deal with a perceived requirement for written description, they must not result in applicants being deprived of legitimate patent protection for *prima facie* generally applicable technical teachings, simply because those applicants had not made multiple specific embodiments of their inventions. The guidelines should instruct Examiners to pay due regard to the scientific and commercial realities of each individual invention, such that the scope of claim is a fair reflection of the applicant's contribution to the art.

Examples given in the guidelines should more clearly reflect typical fact situations.

It is respectfully suggested that the guidelines should be re-drafted to take account of the above points.

Yours sincerely,



Tim Roberts
Chairman, Biotechnology Committee
Chartered Institute of Patent Agents

COPY: T Z Gold, President, CIPA
E Lyndon-Stanford, Chairman, Patents Committee, CIPA
Biotech Committee members

Please copy any reply to:

13 Spring Meadow
Bracknell
Berks RG12 2JP

Phone: 01344 422902 fax 869059
Email: twr@compuserve.com