

6
DG3

Mewburn Ellis

LLP

European Patent Attorneys
European Trade Mark Attorneys
European Design Attorneys
Chartered Patent Attorneys

York House
23 Kingsway
London WC2B 6HP

Tel +44 (0)20 7240 4405
Fax +44 (0)20 7240 9339
mail@mewburn.com

www.mewburn.com

DATE: 31 August 2004
TO: THE REGISTRAR, THE ENLARGED BOARD
COMPANY: EUROPEAN PATENT OFFICE, MUNICH
FAX NO:
YOUR REF:
OUR REF: SMK/misc
SENDER: SIMON KREMER
E-MAIL: simon.kremer@mewburn.com

Number of pages (including this one): 1+5=6 PAGES

If you do not receive all the pages of this fax, please contact us as soon as possible

patents · trademarks · designs · copyright

Message:

This communication is intended only for the use of the addressee and may contain information that is privileged and confidential. If you are not the intended recipient, you are hereby notified that the unauthorised dissemination of this communication may be prohibited by law. If you have received this communication in error, please notify Mewburn Ellis LLP immediately by telephone, fax or e-mail. Thank you.

Mewburn Ellis LLP is a Limited Liability Partnership registered in England (no. OC306749)
Registered Office · York House · 23 Kingsway · London · WC2B 6HP

Mewburn Ellis

LLP

European Patent Attorneys
European Trade Mark Attorneys
European Design Attorneys
Chartered Patent Attorneys

York House
23 Kingway
London WC2B 6HP

Tel +44 (0)20 7240 4405
Fax +44 (0)20 7240 8338
mail@mewburn.com

Partners
Ian Armitage
Hugh Paget
Roger Caldwellbank
Patrick Stoner
Sean Walton
Nigel Hackney
Simon Kiddle
Adrian Braswell
Roger Grimsdew
Ramon Kramer
Joanna Cripps
Robert Watson
Chris Denton
Nicholas Sutcliffe

Consultant
David Harrison

*not CFA or EPA

Assisted by
Sofia Aronai
Richard Clegg
Ray Colairo
Andrew Fearnside
Graham Forrest
Michael Foster
Michael Freeman
Stephen Gill
Susan Harrison
Shelia Hill
Daniel Holt
Alan Hayano
June Lyons
Matthew Naylor
Kathryn Nicholls
Stuart Nield
Alastair Rawlinson
Ian Stuart
Rachel White
Wilhelmus Wytenburg

www.mewburn.com

European Patent Office
D-80298 München
GERMANY

For the attention of: **The Registrar, The Enlarged Board**

31 August 2004

By facsimile

Dear Sirs

Observations on questions referred by the President of the EPO to the Enlarged Board of Appeal – pending as G1/04.
Our ref: SMK/misc

1. Summary and background

At Point 2. below we make observations on the **questions referred under G1/04**. In general terms we submit that the 'narrow' interpretation given to the diagnostic exception of Art52(4) in **T385/86** is the correct one. Conversely the broader interpretation given in **T964/99** is not supported, either by the literal wording of Art52(4), or any other rule of interpretation.

Additionally at Point 4. below we make observations on aspects of the scope of Art 52(4) not covered explicitly by the G1/04 questions, but which we nevertheless hope the Enlarged Board will opine on. These concern measurements made on **artificially created or implanted entities** which are in or on the human body. In general, we consider methods for measuring the properties of such things should not be considered to fall within the scope of Art 52(4). This is because the measurements are not (strictly speaking) "on the human body", and more importantly are not "diagnostic".

As background to the comments below, we believe that Art52(4) has to be seen in the context of Art4(3) - it is the function of the European Patent Organisation to grant patents - and any exceptions to that should be construed narrowly.

Additionally, and importantly, we submit that 'ethical' considerations (in respect of public access to diagnostics) do not necessarily point to a wide construction - the function of the patent system is to encourage and reward innovation and the publication of it. Such innovation will be of benefit in the diagnostics field as much as any other. If a wide construction is taken, then there is a risk that innovation in this field will stagnate - something which is not in the interest of public health.

In any case it is clear that it can not be a fundamental aim of Art54 that physicians can perform diagnoses unfettered by patents: Art52(4) expressly permits new and effective diagnostic **reagents and equipment** to be protected by patents. Patents for such products will inevitably protect methods of using them. Consequently physicians can be practically

or economically deprived of diagnostic methods by patent holders (a point acknowledged, for example in **T426/89**). The rationale is, of course, that given above - if patents weren't permitted then there may be no new diagnostic reagents and equipment at all. Therefore the 'legislative intention' of Art 52(4) must be something more limited than ensuring all diagnostic techniques are unfettered by patents.

In conclusion we submit that the exception under Art52(4) can be correctly applied through application of the principles laid down in T385/86, in the context of the normal rigorous application of Art84 and Art 52(1)-(3).

2 The questions

Qn 1(a) & (b)

We accept that "diagnosis" will almost inevitably be preceded by data gathering or analysis steps i.e. a method may entail:

- (i) data collection,
- (ii) comparison & analysis,

then:

- (iii) diagnostic deduction

The point at issue would seem to be whether these individual elements, and in particular the preceding elements, can be protected as inventions, even if one or more of them is practiced on the human body.

For the reasons given below, we submit that claims which recite some, but not all, of the preceding element (i)-(iii), should not be rejected solely under Art52(4). This reflects the position taken by the Board in **T45/84**:

" a method is a diagnostic method only if it results in a concrete diagnostic result, and that moreover ... neither the diagnostic result in itself nor the method of examination which produces the basis for it is synonymous with the diagnostic method. Thus we may speak of a diagnostic method only if **both** conditions are met" (Reasons 2).

In this respect we would like to stress that the concern raised in T964/99 that the exclusion could perhaps be circumvented by missing out one of the features (i) – (iii) above would appear to be academic rather than real. It is already common practice for EPO examiners to insist that any claim recites **all the essential technical features** required to solve a technical problem with which an invention is concerned. The justification for this seems variously to be given as Art 84 or 56. Therefore it would seem that where an "invention" was in fact a diagnostic method, Art52(4) could not be circumvented by simply missing out one or more (essential) features of it.

Of course in many cases the (i) data collection and (ii) analysis steps above will have utility in methods which are not diagnostic – for example in establishing normal baseline parameters of the human body. Therefore it will be clear that a diagnosis deduction step is not an essential feature of those methods.

Clearly what are or are not essential features needs to be established on a case by case basis. However, considering the "**Referral by the president...**" (EPOJ 5/2004, pp 229-269) [hereinafter "**The Referral**"] at pages 251-252, we believe that it is clear that a number of the claim types exemplified therein would not in fact ever be permitted anyway e.g. under Art 84. For example considering the "taking a picture of a stomach to which a contrast agent has been administered", if the latter was an essential feature of the invention, then the ED would rightly require it be positively recited as a technical feature of the method. If not i.e. if the invention was in fact a method of taking a picture, then clearly that should be patentable.

Thus if it can be established that an **invention resides not in a diagnostic method**, but in one or more (but **not all**) of a method of (i) to (iii) above then it should be permissible to claim it as such. Such claims, **if otherwise patentable** (including with respect to Art 84, Art 56 and Art 57) should not be rejected solely under Art52(4) simply because that invention can be used in the field of diagnosis, and happens to be practised on the human body. Innovation in these areas should be encouraged **just as it is for diagnostic reagents or equipment**.

Although (as noted in T964/99) this might mean that (novel) methods of percussion, auscultation or palpation *per se* could in principle be patentable, we submit that the requirements of Art 84, Art 56 & Art 57 would almost certainly exclude them. Indeed there is also Art52(2) to consider (technical requirement). Therefore these concerns seem to be ill-founded.

Therefore we submit that question 1(a) should be answered in the affirmative, and 1(b) in the negative.

Comparison with surgery

We submit also that the comparison of diagnostics with the case law relating to surgery may not be a helpful one. Inventions in respect of surgery will not generally relate to "preceding elements" as discussed above.

For completeness, we note that the interpretation of Art52(4) in respect of surgery can apparently be summarised as a **single surgical step "within"** a multi-step method should prohibit **the multi-step method** from patentability (see e.g. the "Referral" page 248, paragraph 2; also "Case Law of the Boards of Appeal of the EPO – 4th edition 2001; sentence bridging pages 17-18). However, irrespective of the merits of the relevant decided cases, the summary position is clearly flawed. Considering the multi-step, surgical method, as follows:

A method of treatment comprising:

- (1) preparing a surgical instrument in a novel technical way
- (2) performing surgery

It is clear that a surgeon is **not** prevented from performing the "single" surgical step (2) *per se* by such claims, and therefore there is no rationale for denying the patentability of such claims.

Qn 2

NOT APPLICABLE

Qn 3

We do not have any specific observations on these questions. However we note that they appear to be seeking guidance as to whether a "diagnostic method" can be identified by reference to the level of participation of a physician. With respect, this seems to be a rather indirect. Art52(4) does not mention physician, although the legislators could clearly have done that if they had wished. It must surely be better to consider whether what is being claimed is a diagnostic method i.e. relates to the identification of disease.

We also reiterate the point above - a claim reciting a multi-step method including just one step done by a doctor does not mean the doctor is prevented from doing that one step *per se*.

Qn 4

Again, we do not have any specific observations on these questions. Nevertheless, the key issue here would seem to be why Art52(4) recites "practised on the human body" at all.

Of course all methods of diagnosis must to some extent involve gathering information (directly or otherwise) **about** the human body. Therefore this requirement must mean something narrower than that.

Additionally, it seems to be common ground in the jurisprudence that extra-corporal laboratory tests are patentable because they are not "practised on the human body". However every such test, even if they do not recite it in a claim, **must** have been preceded by some step of obtaining a biopsy or sample i.e. in many cases a surgical step, or a step practised on the body (possibly under medical supervision) – however the existence of such an implied, but unclaimed, step does not affect the patentability of such claims.

Therefore, we submit that the existence of implied, but **unclaimed**, steps (e.g. any of the elements (i)-(iii) above) should not affect the patentability of claims concerned with other properly recite subsidiary elements – if the unclaimed steps were essential features of the method then they would be in the claim.

3 Other aspects of Art52(4) – artificial entities

As noted at the outset, we believe that legal certainty could be improved by a positive indication by the Enlarged Board that methods involving artificial entities (e.g. artificial heart valve, pacemakers, fistulas or shunts etc.) as opposed to the human body or its organs, should not be caught by Art52(4), at least in respect of diagnostics.

We believe this is clearly correct for several reasons.

Firstly, direct measurements in or of (for example) an artificial heart valve, are not "practised on the human body", but rather on an artificial entity attached to it.

Secondly, such measurements are **not "diagnostic"** since they are directed towards the properties of an artificial entity, not the condition of the **patient**. This is analogous to measuring the condition of a plaster cast *in situ* on a broken leg. While the examination might reveal that the cast is damaged, and needs to be replaced (for the sake of the patient) it could not reasonably be argued that the patient was thus "diagnosed" as "suffering" from a "diseased" cast. **This must be indisputable when applying the "narrow" test e.g. of T45/84 above.** However we believe it is also true of the broader test of T964/99.

Finally, these things **are** already distinguishable in patent terms – for example the human body and its elements are not patentable *per se* (EPC 53(a), Rule 23e) whereas artificial entities may be. There is no reason to assume they should simply be equated under Art52(4).

The above, narrower interpretation for artificial implants (in respect of therapy at least) was applied in **T426/89** and we believe also finds support in **T245/87** and **T83/8**. In each case the claims were seen as methods relating to the measurement or operation of technical apparatus. However an arguably broader interpretation was given in **T24/91**, wherein modification of an artificial implant was seen as being caught by Art52(4).

4. Conclusions

The 'narrow' interpretation given to the diagnostic exception of Art52(4) in **T385/86** (and other cases cited above) is the correct one and should be approved by the Enlarged Board.

Yours faithfully



Dr Simon M Kremer
European Patent Attorney