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# Newsletter



**Volume 1, Issue 2**

**April, 2004**

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## **Referral to the Enlarged Board of Appeal concerning diagnostic methods**

The President of the EPO has recently referred a case to the Enlarged Board of Appeal in connection with two apparently contradicting decisions, i.e., T 0385/86 and T 0964/99 concerning the scope of the diagnostic method exception under Art. 52(4) EPC. The case is pending under reference G 1/04. Four questions have been referred to the Enlarged Board of Appeal, [http://www.european-patent-office.org/news/info/2004\\_04\\_08\\_e.htm](http://www.european-patent-office.org/news/info/2004_04_08_e.htm). There are basically two major issues at stake in this referral:

### **All steps versus “one step”**

In case T 0385/86, the Technical Board of Appeal (TBA) interpreted the exclusionary provision of Art. 52(4) EPC narrowly. It is necessary to ascertain whether the method contains all the steps involved in reaching a medical diagnosis. Only those diagnostic methods are excluded whose results immediately make it possible to decide on a particular course of medical treatment. Methods providing only interim results are thus not excluded. Diagnostic procedures like percussion, auscultation or palpation could, in principle, be patentable because they do not constitute a complete diagnosis.

In the view of the TBA in T 0964/99, the exclusion should not be considered to relate to methods containing all the steps involved in reaching a medical diagnosis. Article 52(4) EPC is meant to exclude all methods **practiced on the human or animal body which relate to diagnosis or which are of value for the purposes of diagnosis**. In order to be excluded, it is sufficient that the claimed method contains a method step which serves particularly for diagnostic purposes or which relates to diagnosis, and constitutes in this context an essential diagnostic measure **practiced on the living human or animal body**.

### The criterion that the step(s) must be carried out “on the animal or human body”

In case T 0385/86, it was held that all the method steps which characterize the diagnostic method must be capable of being carried out on the living body itself, and the result must be capable of being read immediately from the step carried out on the human body. Typical examples are e.g. an allergy test in which the abnormal deviation can be detected from a change to the skin, or an endoscopic examination carried out to ascertain liver damage. As soon as some of the steps are carried out outside the human body, the exclusion will not be triggered. Examples are e.g. a measurement of blood pressure, which only reveals any irregularity when compared with a norm, or a radiographic examination with X rays.

In case T 0964/99, the starting point is that only methods practiced on the human body are excluded from patentability, whereas for instance extra-corporal laboratory tests would be patentable. Whether the result can immediately be read from the human body or whether all steps must be carried out on the human body is not relevant. A method step whereby a body sample is taken can fall within the scope of the exclusionary provision of Art. 52(4) EPC, because the claimed step of sampling a substance relates to diagnosis and constitutes in this context an essential diagnostic measure **practised on the living human or animal body**.

It will take some time before the Enlarged Board of Appeal will take its decision. Until then, patent applications which claim in particular body sampling methods will face delays, as the EPO will most probably stay decisions until the matter has been clarified by the Enlarged Board of Appeal.

For more detailed information on this important case, see the extended version of this newsletter on our website <http://www.dcbpatent.com>



### Enlarged Board of Appeal decision in the disclaimer cases, G 01/03, G 02/03

The enlarged Board of Appeal has issued a decision in the important “disclaimer case”.

The answers of the Enlarged Board of Appeal can be summarized as follows:

1. An amendment to a claim by the introduction of a disclaimer may not be refused under Article 123(2) EPC for the sole reason that neither the disclaimer nor the subject-matter excluded by it from the scope of the claim have a basis in the application as filed.

<sup>1</sup> T 0385/86, “Non-invasive determination of measure values/BRUKER”, OJ EPO 1988, 308.

<sup>2</sup> T 0964/99, “Device and method for sampling of substances using alternating Polarity/ CYGNUS, INC.”, OJ EPO 2002, 4.

<sup>3</sup> Art. 52(4) EPC says “Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of [paragraph 1](#). This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.”

2. The following criteria are to be applied for assessing the allowability of a disclaimer which is not disclosed in the application as filed:
- 2.1 A disclaimer may be allowable in order to:
- restore novelty by delimiting a claim against state of the art under Article 54(3) and (4) EPC;
  - restore novelty by delimiting a claim against an accidental anticipation under Article 54(2) EPC;
- an anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention; and
- disclaim subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for nontechnical reasons.
- 2.2 A disclaimer should not remove more than is necessary either to restore novelty or to disclaim subject-matter excluded from patentability for non-technical reasons.
- 2.3 A disclaimer which is or becomes relevant for the assessment of inventive step or sufficiency of disclosure adds subject-matter contrary to Article 123(2) EPC.
- 2.4 A claim containing a disclaimer must meet the requirements of clarity and conciseness of Article 84 EPC.

The entire decisions can be found at [http://legal.european-patent-office.org/dg3/updates/2004\\_04\\_19.htm](http://legal.european-patent-office.org/dg3/updates/2004_04_19.htm)

## [Hearings for BRCA patent oppositions scheduled on 17 May 2004](#)

The proceedings before the EPO Opposition Division (OD) in connection with the opposition against patent EP 0699 754 B1, entitled "Method for diagnosing a predisposition for breast and ovarian cancer" are scheduled on 17 May 2004. The patent covers various predictive screening methods for the breast and ovarian cancer predisposition gene *brca1* in order to identify genetic mutations.

Besides the issue of ordre public and morality (Art. 53(a) EPC), there are a number of other grounds which have to be discussed during the opposition. Insufficiency of disclosure under Art. 83 EPC will be one of the issues to be scrutinized. According to a preliminary and non-binding opinion of the OD, some problems might arise in this context, as, in order to achieve the purpose of the method and make a cancer diagnosis based upon differences between a test sequence and a reference, one needs to know 1) what the reference sequence is; and 2) whether any observed differences are clinically significant.

Novelty and inventive step will also have to be discussed. The issue of diagnostic methods under Art. 52(4) EPC has also been addressed by the opponents. This issue might present some delaying problems, as the exact scope of this provision is currently under review with the Enlarged Board of Appeal. However, in view of the fact that none of the claims contain an explicit sampling step, the problem might be easier to overcome. Arguments during the proceedings will give more insight in this connection.



## Community patent no yet reality

The painstaking history of the Community Patent has not yet come to an end. The Council was unable to reach a final agreement. As could be expected, the language issue seems to be unable to be resolved in Europe. One can question what the situation will be after 1 May, when ten new members join the European Union. According to a press communication sent out after the Competitiveness Council of Ministers in Brussels on 11 March 2004, where a final agreement failed, the main sticking point was how infringements of patents which might arise as a result of mistranslations should be treated.

Commissioner Bolkestein, responsible for the internal market, and thus for all IP issues in the European Union, did not conceal his disappointment. Speaking after the Council, he said "[...] European industry desperately needs access to pan-European patent protection at reasonable cost with minimum red-tape and maximum legal certainty. [...] The failure to agree on the Community Patent I am afraid undermines the credibility of the whole enterprise to make Europe the most competitive economy in the world by 2010. [...] It is a mystery to me how Ministers at the so-called "Competitiveness Council" can keep a straight face when they adopt conclusions for the Spring European Council on making Europe more competitive and yet in the next breath backtrack on the political agreement already reached on the main principles of the Community Patent in March of last year. I must stress that this is despite the very courageous and determined efforts by the Tánaiste Mary Harney to broker a compromise. [...] I can only hope that one day the vested, protectionist interests that stand in the way of agreement on this vital measure will be sidelined by the over-riding importance and interests of European manufacturing industry and Europe's competitiveness. That day has not yet come."



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