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près l'Office européen des brevets*

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**The President**

29 September 2004

**Amicus Curiae Brief in G1/04 (diagnostic methods)**

Dear Mr. Messerli,

The **epi** has discussed the questions presented to the Enlarged Board of Appeal in the case G1/04 and presents its position in the enclosed Amicus Curiae Brief.

Yours sincerely,

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**epi** President

Encl.

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## **Amicus Brief in G1/04 (Diagnostic methods) on behalf of the epi**

The **epi**, highly concerned with the questions presented to the Enlarged Board of Appeal in the case G1/04, herewith presents its position on the interpretation of Art. 52(4) EPC.

### **1.1. Introduction**

It should be emphasized from the outset that according to a generally accepted principle, exclusions from patentability must be interpreted narrowly. This is consequently also true for the diagnostic method provision in Art. 52(4) EPC. Hence, in finding an answer as to the interpretation of the said provision, it is important to reconcile this fundamental principle with the rationale of the exclusion in the EPC.

### **1.2. Rationale of the exclusionary provision of Art. 52(4) EPC**

Art. 52(4) EPC states that "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."

The rationale of Art. 52(4) EPC, as it has been expressed by the Technical Boards of Appeal, has been that medical personnel should not be hindered in performing their medical (health care) activities. It can even be doubted whether this rationale is still of value today. All features of medicine are patentable, except for the medical treatment and diagnostic methods. It is difficult to understand why all methods of diagnosis on the human body should be excluded from patentability, while the products used therein, and the products used for the treatment are perfectly patentable. The exclusion can only be understood from a perspective where the medical profession was seen as being not a business in the commercial sense of the word. This is no longer true today. Furthermore, a growing level of sophistication and involvement of non-physicians in diagnostic methods leaves no further room for the exclusionary provision.

In this context, one can also refer to the fact that until recently, several WTO member states prohibited product patents for pharmaceuticals. The rationale behind this exclusion had equally to do with the importance of health care for the public good. Today, most countries provide for product protection for pharmaceuticals.

At present, the text of the EPC however includes an exclusion. It seems to be the most reasonable solution in such a case to interpret the exclusionary provision in the narrowest possible manner.

### **1.3. All steps v one step**

Case T 0385/86, the Bruker case, has applied a narrow interpretation of the exclusion in Art. 52(4) EPC. Under this case law, all intermediate steps are perfectly patentable. This means, according to case T 0385/86, that to answer the question whether a method is a diagnostic method for the purposes of Article 52(4), first sentence, it is necessary to ascertain whether the method claimed contains all the steps involved in reaching a medical diagnosis. Methods providing only interim results are thus not diagnostic methods in the meaning of Article 52(4), first sentence, even if they can be utilized in making a diagnosis.

The line of reasoning followed by the Technical Board of Appeal in T 0964/99, the Cygnus case, whereby intermediate steps are considered to be "essential diagnostic measures" and are thus to be considered as diagnostic methods within the meaning of Art. 52(4) EPC, has

the advantage of being a solution which is also straightforward, at first glance, but which is not necessarily the most reasonable solution. According to the Technical Board of Appeal in case T 0964/99, any method performed on the human body which relates to diagnosis or which is of value for the purposes of diagnosis, falls within the exclusionary provision.

**A strict application of the Cygnus case could lead to unreasonable decisions.** If we assume that a method is claimed which contains a method step which would fall within the category of Art. 52(4) under the Cygnus interpretation, all method steps in the patent application are threatened to be rejected. **Such a solution does not seem to be in conformity with basic rules of equity, proportionality and reasonableness.**

The Bruker decision presents in this respect the better view. But even if one would prefer to join the line of reasoning of the Cygnus decision, such can only be accepted to the extent that **it should be possible to reject only claims directed to the specific diagnostic method step in the patent, leaving the other method steps in the patent untouched.** A claim directed to a combination of steps including a step within the exclusion category should therefore not be excluded.

Concluding, it can be said that the Bruker case interprets the exclusionary provision of Art. 52(4) very narrowly. Such a narrow interpretation is in conformity with the fundamental principle that exceptions to patentability must be interpreted narrowly.

A strict application of the Cygnus ruling can have illogical and even unreasonable and unfair consequences.

**It is therefore a better solution to defend the argument that indeed claims directed to intermediate steps on the human body can be excluded, but such should not lead to the rejection of all the method steps in the patent, in case these intermediate steps are only an element in the patent application. It seems contrary to the principle of proportionality to reject the entire application in such a scenario.** To the extent that it would not be possible in practice to put such scenario into practice, it would be better to revert to the Bruker decision as the standard test.

#### 1.4. On the human body

Another important feature of diagnostic methods as excluded from patentability under Art. 52(4) EPC is that they must be performed on the human body. Diagnostic methods which are performed outside the human body are not excluded. This cannot be overemphasised. A considerable number of methods which are used in diagnosis are performed outside the human body, since they are in vitro methods. These methods are not envisaged by this case. It is quite surprising to see how much confusion there is in respect of this important feature. In the context of biotechnology, it has been claimed by at least some circles that screening methods, and other (predictive) diagnostic testing methods should be non-patentable on the basis of falling with the ambit of Art. 52(4) EPC. In view of the fact that these methods are performed in vitro, there is, at least in general, no reason to conclude that they are caught by the exclusionary provision of Art. 52(4) EPC.

**In our view, the condition of "on the human body" should be interpreted strictly, in conformity with the principle that exclusions are to be interpreted narrowly.** If the method claimed is not performed on the human body, the exclusion should not be put in action. **Cases where during examination it is held that the sampling step (which is not claimed in the patent application), which would fall within the scope of Art. 52(4) EPC, can be implied from the description, and thus turns the in vitro method claimed into an excluded method, are bad practice, and do not deserve further application, for a number of reasons.**

First of all, by holding that a sampling step is implied from the description, patent protection would be refused for an in vitro method without a sampling step being claimed. Such

rejection is an undue limitation. **Going back to the rationale of Art. 52(4) EPC, that the medical profession should not be hindered in their medical activities, it is difficult to see how a medical practitioner could indeed be hindered in his activities, if the invention concerns in vitro methods, and the sampling step as such is not even claimed. This leads inevitably to the conclusion that the sampling done by the physician could in such a hypothesis never be an infringement, and thus no hindrance to the medical activity.**

It can secondly also seriously be questioned whether an in vitro method, which for the sake of argument fulfils all patentability requirements, should be refused patent protection, because the description implies a sampling step, which is not claimed, and which is anything but novel and inventive. Such an interpretation would unduly hinder development of new in vitro diagnostic methods. In many in vitro diagnostic methods, a sample is required to carry out the method. **Allowing exclusion of the in vitro method from patent protection on the basis of a not claimed but implied in vivo method, would in fact extend the exclusionary provision of Art. 52(4) EPC to in vitro methods, and this can never have been the intention of the legislator.**

Case T 0964/99, however, holds that "the taking of a body sample for the purpose of a medical examination belongs to a fundamental diagnostic activity, regardless of the technical means used [...]. For these reasons, 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."<sup>1</sup> In other words, one could come to the conclusion after reading this case, that, since sampling is an essential step, any method, which implies a sampling, should be excluded. We have said earlier that we think this is not sound practice and should not be followed. **It is difficult to see how a simple sampling step should be capable of excluding an entire novel, inventive and industrially applicable method from being patentable. Such a solution would be far out of proportion to the rationale of the exclusionary provision of Art. 52(4) EPC, which did not have as a goal to exclude from patentability all methods which are relating in a direct or more distant way to diagnosis.**

But moreover, it is also necessary to put this ruling into perspective, before generalisations are being made as to the scope of the exclusionary provision of Art. 52(4) EPC, as in our view, **case T 0964/99 does not lead us to make such a generalisation.** In our view, this ruling must be put in perspective, in that the invention claimed in that case related to, amongst others, a very sampling method. In other words, the sampling as such was an essential part of the invention claimed. If that is compared to a method whereby a cell, DNA, or blood is sampled in order e.g. to perform a screening, and where the screening method is the essential part of the invention as claimed, one could conclude that the situation is to be decided differently. The Technical Board of Appeal in case T 0964/99 held that sampling belongs to a fundamental diagnostic activity, in a case where the sampling was essential in the invention.

**It would go too far to conclude that an implied sampling step in an invention has the same value to the invention, and therefore, that the invention as a whole should be excluded from patentability.**

### 1.5. The presence of a physician

The distinction which is made between whether a physician is present or not, is another issue which requires clarification in this referral. Once again, the underlying rationale of the exclusionary provision, i.e., that physicians may not be hindered in their activity, can be of assistance to help clarifying this matter.

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<sup>1</sup> T 0964/99, at 5.2 of the reasons.

Starting from that rationale, and the protection of the activities of physicians, there is at first sight an argument in saying that in order to be excluded from patentability, a physician must perform the method. This must also be seen in the context of the fact that only methods “on the human body” are excluded from patentability, and traditionally, some of these methods have been reserved for the physician.

Taking into account the rationale of the exclusionary provision, it can be argued that not only those acts on the human body performed by a physician are excluded, but also those activities carried out on the human body under his supervision. This fits within the rationale that physicians should not be hindered in their medical activities, which includes logically also activities performed under his supervision. It must be admitted, however, that the term “under his supervision” is not very clear, and it is difficult to see how during patent examination it can be established whether a specific activity has been or will be carried out under the supervision of a physician.

As such, requiring the presence of a physician would thus be in conformity with the rationale of the exclusionary provision. It must be observed, however, that also this provision is to be read in the context of the limitation that only methods performed on the human body are excluded. As we have argued earlier, it is necessary to strictly limit the exclusion to methods performed on the human body. In our view, this implies that there is no room for rejecting claims, which contain an implied step.

Secondly, it can also not be accepted that an entire method claim would be rejected which contains a sampling step performed on the human body. To the most, the sampling step can be rejected. The in vitro method should be patentable. This remains unequivocally applicable to activities carried out by a physician or under his supervision.

**This means that only those explicit method steps, which are performed on the human body by a physician or under his supervision can be excluded from patentability, leaving the other method steps within the claimed method untouched. All diagnostic methods performed by a physician, or under his supervision, outside the human body, can under no circumstances fall within the scope of Art. 52(4) EPC.**

## 1.6. Conclusion

The Bruker case responds closest to the requirement of legal certainty and the criterion that exceptions to patentability are to be interpreted narrowly. Following the Cygnus decisions would for multiple reasons be contrary to the principle of proportionality, equity and reasonableness.

The only diagnostic methods which should be excluded from patentability, according to a correct interpretation of the provisions of the EPC are those methods where an essential step of the method, leading directly to a diagnostic is performed on the human body by a practitioner or under his direct supervision.

The presence of a physician should be linked, strictly, to method steps performed on the human body. Any other interpretation, which would provide a wider exclusionary scope is against the basic principles mentioned earlier.