FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INDUSTRIELLE

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Secrétaire Général

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By mail and email
mailto:pmesserli@epo.org

Dr Peter Messerli,
Director of EPO DG 3 & Chairman of
Enlarged Board of Appeals
Erhardtstraße 27
D-80298 MUNCHEN
ALLEMAGNE

Re. Amicus Brief for Case G 1/04 before the Enlarged Board of Appeal of the European Patent Office

Dear Dr. Messerli,

In the name of FICPI, I am pleased to submit herewith for your consideration a document prepared by our Federation for consideration in relation to the above issue.

A copy of this document is also being sent to Mr Gert Kolle, EPO Director of International Legal Affairs, and to the Registrar of the Enlarged Board of Appeals.

Yours sincerely,

Jean-Jacques Joly

Enc.

c.c. Gert Kolle (mailto:gkolle@epo.org)

c.c. Registrar of Enlarged Board of Appeals

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AMICUS BRIEF

for CASE G 1/04

before the ENLARGED BOARD OF APPEAL

of the EUROPEAN PATENT OFFICE

FICPI, the International Federation of Intellectual Property Attorneys, representative of the profession in private practice, including national Patent Attorneys, European Patent Attorneys and Patent Agents in all EPC member countries, welcomes the invitation of the Enlarged Board of Appeal (EnBoA) in the Communication of 8th. April, 2004 to file written statements in accordance with Art. 11b of the Rules of Procedure of the Enlarged Board of Appeal for case G 1/04.

1. The Background to G 1/04

With the present referral to the EnBoA, the President of the EPO has asked for clarification of the patentability requirements for diagnostic methods for humans and animals. According to Art. 52(4) EPC, diagnostic methods "*practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application*". In the second sentence of this paragraph it is stated that this provision "*shall not apply to products, in particular substances or compositions, for use in any of these methods.*"

In the case law of the EPO Technical Boards of Appeal, this provision has been interpreted so as to exclude only those diagnostic methods in which all steps of the claimed method, including the actual diagnosis *per se*, are carried out on the human or animal body. This established case law has been well summarised in the present referral by the President of the EPO (with the leading case for the present referral, T 385/86).

Therefore, diagnostic methods in which the human or animal body itself is subjected to one or more procedures within the method (e.g., taking samples or recording body states (NMR, X-ray, insulin concentrations, heart data, etc.) have been regarded as being industrially applicable unless all such steps including the diagnosis itself are to be carried out on the body.

In Decision T964/99 (OJ EPO 2002, 4), the principles behind this established case law have been questioned. Although T964/99 could have been decided on the basis of the established case law in almost the same way, BoA 3.4.1 felt it necessary to include in its decision an "*obiter dictum*" expressing the view that "*the taking of a body tissue sample for the purpose of a medical examination belongs to a fundamental diagnostic activity, regardless of the technical means used, be it a spatula for taking a swab or smear, a syringe for taking a blood sample, or, as in the present case, a iontophoretic current forcing a substance through the skin.*" The 3.4.1 BoA held that a claim containing a "*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.*" However, if the taking of a tissue sample is sufficient to exclude patentability, "*regardless of the technical means used*", it is difficult to understand why sampling with electronic means (by NMR, X-rays, etc.), which also involves the human or animal body in the essential sampling step, should be treated differently, as stated in paragraph 6.2 of the Reasons for the Decision. Logically, **with such a broad interpretation of Art. 52(4) EPC, all diagnostic methods would have to be regarded as not being susceptible of industrial application.**

FICPI considers that the view taken in T 964/99 is not only incorrect in its interpretation of the law but also that such a reversal of established case law is completely unnecessary and damaging to the legal certainty of the European patent system. Moreover, a change of practice in line with T 964/99 would not result in greater freedom for physicians, but rather in a setback for innovators and a reward for imitators.

2. The wording of Art. 52(4) EPC only excludes diagnostic methods performed on the human or animal body. This wording was deliberately chosen in order not to cover all diagnostic methods.

It is a well-established principle that patentability exclusions are to be interpreted narrowly. As only diagnostic methods practised on the human or animal body are excluded by the Convention, it must follow that not *all* diagnostic methods are excluded, because then the words "*practised on the human or animal body*" would be superfluous. (In fact, TRIPs (Art. 27(3)(a) and PCT (Rule 39.1(iv)) do not contain this additional wording.) Therefore, from the text of Art. 52(4) alone it is evident that *all* diagnostic methods are not excluded.

The present exclusion was introduced after the Strasbourg Convention. In fact it was mainly the wording of PCT Rule 39.1 which led to the inclusion of Art. 52(4) into the EPC. The first two drafts of the EPC approved by the Inter-Governmental Conference (Working Party I) contained a requirement identical to Rule 39.1 PCT. However, the working papers of the conferences show that discussion of this topic related almost exclusively to the medical treatment aspect of the exclusion, not to the diagnostic aspect (e.g. Documentation of the Munich Diplomatic Conference M/PR/I ("Article 50(52)") and

Appendix I ("2. Patentability (Art. 50-55)"). Following a proposal of the French delegation, the term "*diagnostic methods*" was modified by the limiting phrase "*applied to the human or animal body*" (Moufang, IIC 24(1) (1993), 29, relying on the Historical Documentation). During the Munich Diplomatic Conference only the reasoning behind the exclusion ("*lack of industrial application*") was introduced into Article 52 EPC. (*ibid.*)

FICPI shares the view of many commentators on Art. 52(4) EPC (e.g., (as a recent example of many others) Crespi, The CIPS Journal, March 2004, 146-148) that lack of industrial applicability is not a logical foundation for this exclusion and that this exclusion, like any other exclusion, has to be interpreted narrowly, as an exclusion to the general principle that inventions are patentable.

3. A change in practice with respect to diagnostic methods as outlined in T 964/99 would invalidate a great many Patents that relate to diagnostic methods performed *in vitro* on bodily fluids.

Maintaining and improving legal certainty have always been major concerns of FICPI. Like any legal instrument, the provisions of the EPC are open to interpretation. This, of course, applies to the provisions that exclude certain classes of subject matter from patentability. In the opinion of FICPI, where EPO Boards of Appeal have been following the well-established principle that exclusions to patentability should be interpreted narrowly, other Boards should refrain from adopting a narrower interpretation unless the established broader interpretation is clearly unsustainable, as this would inevitably lead to European Patents which had been properly granted under the previous case law becoming invalid, in many cases incurably invalid.

This would not only be unfair to specific patent proprietors but would seriously damage the credibility of the European Patent system.

In the specific case of diagnostic procedures, many European Patents have been granted with claims covering *in vitro* diagnostic methods performed on bodily fluids or tissue samples. Many of these Patents are held by SMEs and many of them have been licensed, e.g., to manufacturers of diagnostic kits or to sample-testing laboratories. If the interpretation of the exclusion adopted in T964/99 were upheld these Patents would be invalid and any licences worthless. This would have a serious negative economic impact on both patent proprietors and licensees without any compensating benefit.

In fact, the only beneficiaries would be those who would take advantage of the situation by copying the methods covered by the no longer valid Patents.

4. **To sum up, based on the literal wording of Art. 52(4) EPC and the historical background to this provision, the lack of any perceived need to reverse the previously-established case law, the damage to the credibility of the European Patent system that will certainly occur if a whole group of patents is suddenly rendered invalid, and the unfair effect that this would have on the proprietors of those patents and the resulting benefit to imitators, FICPI strongly urges that the Enlarged Board of Appeal should confirm that the previous case law, e.g. as set out in T 385/86, is correct. FICPI's answers to the President's questions in the present referral are therefore as follows:**

1a. Are "diagnostic methods practised on the human or animal body" within the meaning of Article 52(4) EPC (hereinafter: "diagnostic methods") only those methods containing all the procedural steps to be carried out when making a medical diagnosis, i.e. the examination phase involving the collection of relevant data, the comparison of the examination data thus obtained with the standard values, the finding of any significant deviation (a symptom) during that comparison and, finally, the attribution of the deviation to a particular clinical picture (the deductive medical decision phase).

FICPI's answer: YES

or

1b. Is a claimed method a "diagnostic method" even if it only contains one procedural step that can be used for diagnostic purposes or relates to the diagnosis?

FICPI'S answer: NO

2. If the answer to question 1b is in the affirmative: Does the claimed method have to be usable exclusively for diagnostic purposes or relate exclusively to the diagnosis? According to which criteria is this to be assessed?

FICPI's answer: No answer, as the answer to question 1B is in the negative.

3a. Is a claimed method a "diagnostic method" if

i) it contains at least one procedural step considered as essential for a "diagnostic method" and requiring the presence of a physician (Alternative 1), or

ii) it does not require the presence of a physician but presupposes that a physician bears the responsibility (Alternative 2), or

iii) all procedural steps can also or only be practised by medical or technical support staff, the patient himself or an automated system (Alternative 3)?

FICPI's answer: None of the above Alternatives 1, 2 and 3 is as such sufficient to define a diagnostic method according to Art. 52(4) EPC.

Certain samples of bodily materials are normally provided by the patient himself without intervention of medical staff. Thus, in normal circumstances, urine, hair, skin cells and saliva samples, for example, are provided by the patient without such intervention, however, occasions arise where even the taking of these samples does involve medical staff, for example, if the patient is unconscious at the time the sample needs to be taken. Certain types of samples may sometimes be taken by medical staff and at other times delivered by the patient without assistance from medical staff. For example, a sample of saliva may be taken by a nurse or physician using a swab or alternatively delivered by the patient himself. But the sample is the same in both cases.

In its Decision, the Board in T 964/99 clearly saw the logical absurdity in distinguishing between bodily samples taken with the assistance of medical staff and the same bodily samples provided by the patient without any such assistance, and came to the conclusion that regardless of by whom the samples are taken, *any* procedure involving the taking of bodily samples is a diagnostic procedure excluded by Art. 52(4) EPC. Thus, the delivering of a urine or saliva sample by a patient without medical intervention and the subsequent analysis of that sample by a commercial laboratory is construed as a diagnostic method "practised on the human or animal body". But, in this case, no step is practised on the human body so such a conclusion is inconsistent with the clear wording of the Article.

Also, the distinction drawn in T 964/99 between a procedure that includes the step of a patient delivering a sample of bodily fluid without medical intervention on the one hand (which by that Decision is considered unpatentable) and the monitoring of a bodily condition using electronic means on the other hand (which is considered patentable) is bizarre, given that in the former case no medical personnel are involved in taking the sample but in the latter case the monitoring step has to be performed by trained medical staff.

Moreover, it should not be forgotten that the reason that diagnostic methods practised on the human body are not patentable is that they are not considered to be industrially applicable. However, the analysis of bodily samples by commercial laboratories is quite clearly an industrial procedure.

3b. If the participation of a physician (by being present or by bearing the responsibility) is decisive, does the physician have to participate in the procedural step practised on the body, or does he only have to participate in any procedural step considered as essential for a diagnostic method?

FICPI's answer: Again, as above for 3a, the physician has to participate in all procedural steps, including the diagnosis, to fall under Art. 52(4) EPC.

4. Does the requirement "practised on the human or animal body" mean that the procedural steps take place in direct contact with the body and that only such steps practised directly on the body can provide a method with the character of a diagnostic method.

FICPI's answer: YES

or is it sufficient if at least one of the procedural steps is practised directly on the body?

FICPI's answer: NO.

Respectfully submitted,

FICPI