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To the kind attention of:
The Registrar of the Enlarged Board of
Appeal

Via fax: 0049 89 2399-4465 (4 pages)
Confirmation copy by TNT COURIER

Observation under Art 11b Rule of Procedure of the EBA

Your ref.: G 1/04

Our ref.: Diagnostic method

Sirs,

Written statement in accordance with Rule 11b RP of EBA concerning the pending Opinion
G1/04 is herewith filed.

As thoroughly discussed in the Referral by the EPO's President to the EBA, the divergent
decisions are decisions T 964/99 and T 385/86 (and decisions which take their line of
arguments), and the point of Law at issue relates to the different interpretation given by the
two competent Boards to the term "diagnostic methods practiced on human or animal body"
within the meaning of Art. 52(4) EPC".

As clearly stated in point 6.2 of decision T 964/99, this decision does not affect the
patentability of technical methods identical or equivalent to the method considered in decision
T 385/86, because the two types of methods considered in the divergent decisions are
substantially different. Whereas the method according to T 385/86 does not comprise any
step which is explicitly practiced on the human or animal body, the method of T 964/99
comprises an essential step directly practiced on the human body, namely the extraction of
body substances by iontophoresis. Although the remaining steps of the method are
presumably carried out *in vitro*, the method in its entirety derives the "medical" nature in the
meaning of Art. 52(4) EPC from this single step performed *in vivo*.

In the Board argumentation, T 964/99 is consistent with several earlier decisions either in the
therapeutic field, see e.g. T 35/99, T 82/93, or T 820/92 (Contraceptive method), or in the
diagnostic field, see T 329/94 or T 655/92.

In all these cases, a method of treatment that a priori could be qualified as technical and
susceptible of patent protection, acquired a "medical" nature under Art 52(4) EPC, from one
single step directly practised on the human body.

It is however very relevant to stress that all these previous cases share one decisive feature.
Namely, the step practiced *in vivo* is in itself a "medical" step, either therapeutic or surgical,

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which would likely be excluded from the patent protection even if performed alone and separated from any diagnostic purpose.

This is the case of T35/99, where the step of inserting a catheter was regarded as a surgical method regardless its specific final purpose. The Board stresses (page 8, last paragraph) that

"a claim is not allowable ... if it includes at least one feature defining a physical activity or action which constitutes a "method of treatment of the human body by surgery or therapy", and (emphasis added) it is irrelevant whether the method in question is susceptible of being carried out in isolation or only in combination with other methods which together achieve the intended medical purpose".

Case T 820/92 deals with the treatment of female mammals with LHRH composition in order to obtain a contraceptive effect. A contraceptive treatment performed on human is not excluded from patentability as "medical" treatment, but for lack of industrial application. In this case however, the method in its entirety acquired "medical" nature (therapeutic) from the concomitant treatment with steroids which was intended to avoid the ill consequences of the LHRH administering. This step, which amounts in itself to a therapeutic prophylactic treatment such as a vaccination, would be excluded from patentability also if performed alone and outside of any contraceptive purpose.

Decision T 964/99 also cites case T 82/93. However, the circumstances dealt with in this earlier decision would appear to be completely different from those of T964/99. The method according to T82/93 was a multi-step method, characterized by a continuous functional interaction between an essentially technical activity (i.e. adapting the functioning of a pace-maker to the contingent needs) and the activity of measuring the ventricular systolic pressure, both activities inextricably contributing to the final therapeutic effect. No such a functional continuous relationship between the technical and medical steps is envisaged in case T964/99.

Other, more relevant cases are to be found in the diagnostic field.

In case T329/94, the competent board made clear that a blood extraction method considered **per se** would fall under the exclusion of Art. 52(4) EPC, notwithstanding the final purpose of the multi-step method comprising the blood withdrawal. Thus, the step of blood extraction through a venous blood extraction point, which is essentially an invasive intervention, was qualified by the board as a surgical step in itself.

In case T 655/92, an NMR investigative method carried out without any direct contact with the human body, acquired the "medical" character from the injection of a contrast agent necessary for the success of the analysis. Due to the toxic properties of the contrast agent, which could result in a fatal outcome of the treatment, this step could only be carried out under the strict medical control. It is evident that the "medical" nature of this step would be maintained also if the step were performed alone, since the toxicity of the used agent was independent from the diagnostic purpose.

It seems therefore that the step carried out *in vivo*, must be "medical" in itself, and cannot contribute to the "medical" qualification of the whole treatment for the sole reason that it is performed *in vivo*.

According to this Case Law, the decisive point to consider in evaluating cases similar to that of T 964/99 is whether an *in vivo* step, which is part of an otherwise patentable diagnostic method, is to be considered, already when taken alone, as an action excluded from the patentability under Art 52(4) EPC, regardless of the intended scope of the whole multi-step method. In the practical case, the relevant question would appear to be whether the step of extraction of substances or metabolites from the human body by way of iontophoresis is to be considered in itself a therapeutic or surgical method.

The Board avoided to give any answer to this question by formulating a very broad definition of "diagnostic method", which automatically recruits or integrates within the very concept of "diagnostic method" any step, though preliminary or accessory, relating to the diagnosis or of value for the purpose of the diagnosis.

Without entering into the merit of the semantic reasons which supported the Board in its decision, it seems that the Board's broad interpretation of "diagnostic method" would lead to the unacceptable result of qualifying as "diagnostic" also a method which, as claimed, does not comprise any diagnosis at all.

This approach would appear to be inconsistent with a basic provision of patent protection under the EPC that is that the scope of the protection conferred by a patent is given by the wording of the claims, interpreted, if need be, in the light of the description (Article 69 EPC). However, this interpretation can never have the effect of arbitrarily integrating into the scope of the protection specific subject-matter, either activities or products, that the applicant had voluntarily excluded from the wording of the claims and accordingly from the scope of protection. If a claim defines a technical process preliminary to or preparatory for the very diagnosis, without citing or claiming any action representing the actual diagnosis, then this "prohibited" step cannot be regarded as comprised within the scope of protection. Accordingly, any interpretation of the concept of "diagnostic method" intended to arbitrarily integrate this essential step within the ambit of the claim and declare the claim unpatentable in its entirety under Art 52(4) EPC, would appear to be very questionable.

According to this approach, actions such as sampling urine or saliva, measuring body temperature or simply collecting information about the health-history of a patient or even of the patient's family, which step is definitely of value for the diagnosis of a genetic or tumor disease, would result to be each one a "diagnostic action" in itself.

Moreover, although, admittedly, Art 52(4) EPC uses a different wording to indicate and exclude therapeutic, surgical and diagnostic methods of the human or animal body, it seems reasonable to think that the legislator intended to apply the same or equivalent criteria to the three medical treatments. In fact all these three exclusions are based on the same juridical historical reasons and are intended to achieve the same goal: that is, avoiding patent bars to

the medical activity. For this reason, the same broad interpretation of "diagnostic" given in T964/99, if accepted, should also be applied to "therapeutic" and "surgical". This would easily result in a significant decrease of the legal certainty in the whole technical area. In fact the meaning of "relating to" or "of value for" would appear to be very subjective and open to many different interpretations.

In the light of aforementioned considerations, it seems reasonable to conclude that in order that an analytical method be considered a diagnostic method *in vivo* it must at least comprise the very diagnosis, i.e. the very step of making a diagnosis, and this step be practiced directly on the human or animal body. Methods not comprising this essential step should not be considered diagnostic, though performed *in vivo*.

Moreover, an *in vivo* procedural step may convert an otherwise patentable diagnostic method into a method excluded under Art. 52(4) EPC only if such a step can be qualified as "medical" in itself, and would be excluded from patentability regardless of the intended diagnostic purpose.

Respectfully,



Claudio Germinario
European Patent Attorney