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For the Attention of the Registrar of the Enlarged Board of Appeal

By fax to +49 (89) 23 99 4465
Confirmation to follow by post: Yes

31 August 2004

Your ref.: G 1/04
Our ref.: 167.03

Dear Sirs,

President's Referral to the Enlarged Board of Appeal of the European Patent Office
Case G 1/04
Statement by Amersham plc (now trading as GE Healthcare, Biosciences)

On behalf of Amersham plc ("Amersham"), now trading as GE Healthcare, Bio-Sciences, I file herewith a statement under Art 11b(1) of the Rules of Procedure of the Enlarged Board of Appeal. I invite the Enlarged Board to take the contents of the statement into account when considering the issues referred by the President of the EPO.

Please stamp and return the enclosed EPO Form 1037 as evidence of safe receipt.

Yours faithfully,

A. G. Sheard
Authorised Representative

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PRESIDENT'S REFERRAL TO THE ENLARGED BOARD OF APPEAL OF THE EUROPEAN PATENT OFFICE

CASE G 1/04

STATEMENT BY AMERSHAM PLC

1 INTRODUCTION

(1) In accordance with Art 112(1)(b) EPC, the President of the European Patent Office has referred points of law relating to the interpretation of the term "diagnostic methods practised on the human or animal body" within the meaning of Art 52(4) EPC to the Enlarged Board of Appeal.

(2) This paper constitutes a statement by Amersham plc ("Amersham"), now trading as GE Healthcare, Bio-Sciences, under Art 11b(1) RPEBA.

(3) Amersham is made up of three businesses, which are focused on enabling molecular medicine, with the aim of bringing new discoveries about the molecular basis of disease into clinical practice in the diagnosis and treatment of disease. Amersham's medical diagnostics business is a leading pharmaceutical provider of diagnostic and predictive imaging products and services, specialising in the field of in vivo diagnostic products for the early and accurate detection of disease. Amersham focuses on: the management of heart disease, circulatory disease and stroke; degeneration of the brain such as is seen in Alzheimer's disease and Parkinson's disease; and a range of cancers. In addition, Amersham is a major provider of therapy products to treat prostate, thyroid and other cancers.

(4) Amersham's life sciences businesses (discovery systems, protein separations and molecular diagnostics) are leading global providers of integrated systems and solutions (instruments, reagents, software) for disease research and drug discovery, development and manufacture. In discovery systems, Amersham provides high throughput systems to help researchers in industry and academia understand the genetic and molecular basis of disease and speed up their drug development. In protein separations, Amersham provides research and manufacturing technologies that enable pharmaceutical and biotech companies to bring new biological drugs to the market. Amersham has recently established a molecular diagnostics business focusing on *in vitro* diagnostic products.

(5) Particularly because of its medical and molecular diagnostics businesses, Amersham has a keen interest in the issue before the Enlarged Board and wishes to make this contribution to aid the Enlarged Board's deliberations.

2 ADMISSIBILITY OF THE PRESIDENT'S REFERRAL

(6) Referrals to the Enlarged Board by the President are governed by Art 112(1)(b) EPC. They can be made "where two Boards of Appeal have given different decisions" on a question of a point of law. In Section IV of the Grounds supporting his Referral, the President raises the question of whether in this case the different decisions have been made by two Boards of Appeal or by the same Board. It is clear, we submit, from Section III of the President's Grounds that Decisions **T385/86** and **T964/99** are different, but both decisions originate from the Technical Board designated 3.4.1. The President has therefore considered in Section IV whether the requirement that the decisions be from "two Boards of Appeal" is satisfied and, therefore, whether the Referral is admissible.

(7) We urge the Enlarged Board to find that the requirement is satisfied and that the Referral is admissible. We agree with the President's comments in Section IV of his Grounds, and we wish to add the following remarks.

(8) In **G5/83** the Enlarged Board established that the provisions of The Vienna Convention on the Law of Treaties, concluded on 23 May 1969 (the "Vienna

Convention"[1]), should apply to the EPC even though the provisions of the Vienna Convention do not apply to the European Patent Convention *ex lege*[2].

(9) Arts 31 and 32 of the Vienna Convention provide how a treaty should be interpreted. The effect of these Articles was summarised by the Enlarged Board in G5/83 in the following terms[3]:

> (1) The treaty must be interpreted in good faith.
>
> (2) Unless it is established that the Contracting States intended that a special meaning should be given to a term, the terms of the treaty shall be given their ordinary meaning in their context and in the light of the object and purpose of the EPC.
>
> (3) The context, for this purpose, is the text (including the Preamble and Implementing Regulations) and any agreement made between all the parties in connection with the conclusion of the treaty (e.g. the Protocol to Article 69 EPC).
>
> (4) There shall also be taken into account:
>
> – any subsequent agreement between the parties regarding interpretation or application of the provisions;
>
> – any subsequent practice which establishes the agreement of the parties regarding interpretation;
>
> – any relevant rules of public international law.
>
> (5) The preparatory documents and the circumstances of the conclusion of the treaty may be taken into consideration
>
> – in order to confirm the meaning resulting from the application of the previous rules or
>
> – to determine the meaning, when applying those rules either leaves the meaning ambiguous or obscure or leads to a manifestly absurd or unreasonable result.

(10) The primary rule of interpretation may therefore be further summarised to be one of *good faith, contextual and purposive construction*. The purpose is to be taken primarily from the EPC. In the present case, the *purpose* of Art 112(1)(b) EPC is to be found in the *context*, namely in the opening words of Art 112 itself. Referrals can be made to the Enlarged Board either "to ensure uniform application of law, or if

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[1] Accessed on 14 June 2004 12:27 at http://www.un.org/law/ilc/texts/treaties.htm
[2] G5/83, Reasons ¶¶ 3-4
[3] G5/83, Reasons ¶5

an important point of law arises"[4]. (The present Referral is, incidentally, for both purposes.) It is not believed that the Contracting States intended that any special meaning should be given to the term "two Boards of Appeal"; neither is there believed to be any subsequent agreement or practice or any relevant rules of public international law which have a bearing on the matter. Therefore, the meaning that arises from the context and purpose of the term should prevail. Art 112(1)(b) better fulfils its purpose if the term "two Boards of Appeal" is interpreted as being read with the notional rider *whether similarly or differently designated*. Indeed, it is submitted that the term best fulfils its purpose when read with the further notional rider *and whether similarly or differently constituted*, for it makes no sense to exclude from the ambit of Art 112(1)(b) EPC the resolution of conflicting decisions of the same members of the Boards of Appeal[5].

(11) The mere designation as Board "3.4.1" of each Technical Board whose decisions are involved in the present Referral does not mean that the Technical Boards are not "two Boards" as required by Art 112(1)(b) EPC. That designation is, as explained by the President, merely part of the business distribution plan of the EPO, and is not a designation of identity for the purpose of Art 112(1)(b) EPC.

(12) We therefore urge the Enlarged Board to find that Decisions T385/86 and T964/99 are decisions of two Boards of Appeal. To hold otherwise would, we believe, defeat the supremely useful purpose of Art 112(1)(b) in resolving conflicting decisions of Boards of Appeal.

3 THE LEGAL FRAMEWORK

(13) The present Referral is concerned with part of Art 52(4) EPC. Art 52(4) is itself a rider on Art 54(1) EPC:

> *Article 52*
> Patentable inventions
>
> (1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

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[4] Art 112(1) EPC

[5] Otherwise, the result would be that all decisions issued by any one Board of Appeal composition (such as that designated "3.4.1") must always be entirely self-consistent and could never be submitted to the Enlarged Board. This cannot have been the intention of Art 112(1)(b).

...

> (4) ... 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. ...

(14) Diagnostic methods practised on the human or animal body are not *directly* excluded from patentability. Rather, Art 52(4) EPC establishes a legal fiction that such methods "*shall not be regarded*[6] *as* inventions which are susceptible of industrial application". Art 52(1) EPC actually does the work of excluding them from patentability[7].

(15) The Referral is concerned in particular with the meaning of the phrase "diagnostic methods practised on the human or animal body". Neither the Implementing Regulations to the EPC nor any of the ancillary regulations clarifies or assists with the interpretation with this phrase.

(16) The two Decisions at the heart of the Referral, namely **T385/86** (Non-invasive measurement/BRUKER) and **T964/99** (Device and method for sampling of substances using alternating polarity/CYGNUS, INC), principally establish the conflict in the way Art 52(4) EPC has been interpreted by the Technical Boards of Appeal in relation to diagnostic methods. We shall have more to say about the different interpretations used in those two cases in due course.

(17) At this point, we shall review the principles of construction that ought to govern Art 52(4) EPC, which embodies an exclusion to patentability.

4 CONSTRUING ART 52(4) EPC

4.1 Legal Considerations

(18) It is frequently stated that exclusions to patentability must be construed narrowly. Authority for this proposition, applying specifically to Art 52(4) EPC as well as other exclusions in the EPC, can be found repeatedly in the case law of the Boards of Appeal, for example:

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[6] The wording implies that such methods are inherently susceptible of industrial application, otherwise there would be no need to "regard them" as the opposite.

[7] This scheme would change under the Basic Proposal for Revision to the EPC (CA/100/00 e), which would delete Art 52(4) EPC and incorporate a corresponding direct exclusion as Art 53(c).

T385/86
3.2 ... Like any exclusion clause, Article 52(4), first sentence, must be narrowly construed, a fact underscored by the statement in the second sentence that the exclusion from patentability does not apply to products for use in such methods.

T320/87
6. Like any exception to a general rule of this kind the exclusion of "essentially biological" processes for the production of plants (or animals) has to be narrowly construed.

T780/89
3.2 ... Article 52(4) EPC was, however, to be construed narrowly...

T19/90
4.5 Firstly, the Examining Division did not take duly into account that Article 53(b) EPC is an exception, for certain kinds of inventions, to the general rule under Article 52(1) EPC that European patents "shall be" granted for all inventions which are susceptible of industrial application, which are new and which involve an inventive step. Any such exception must, as repeatedly pointed out by the Boards of Appeal, be narrowly construed (cf. in particular T 320/87, point 6, OJ EPO 1990, 76).

T356/93
8. From the historical documentation relating to the EPC it appears that the view according to which "the concept of patentability in the European patent law must be as wide as possible" predominated (see document IV/2071/61-E, page 5, point 2, first paragraph). Accordingly, the exceptions to patentability have been narrowly construed, in particular in respect of plant and animal varieties (see, for example, T 320/87 and T 19/90 supra). In the board's view, this approach applies equally in respect of the provisions of Article 53(a) EPC.

T329/94
3. From the jurisprudence of the boards of appeal, the following principles emerge:
With regard to exceptions to patentability, Art. 52(4) EPC should be construed narrowly (T 385/86, OJ EPO 1988, 308, point 4.1).

T789/96
2.2.1 Under Article 52(4) EPC, methods for treatment of the human or animal body by surgery or therapy are not considered inventions which are susceptible of industrial application, and are therefore excluded from patentability. Such exclusions are normally construed narrowly, and therefore not applied to methods having no therapeutic effect (see T 144/83, OJ EPO 1986, 301, Reasons point 3).

In this connection, the Enlarged Board of Appeal has expressly stated in decision G 5/83 (OJ EPO 1985, 64, Reasons point 22) that "The intention of Article 52(4) EPC ... is only to free from restraint non-commercial and non-industrial medical and veterinary activities".

(19) The Enlarged Board itself has also construed the exclusion to patentability embodied in Art 52(4) EPC narrowly, as is evident from the decision and reasoning (especially at ¶22) of **G5/83**.

(20) The principle that exclusion clauses to patentability generally, and Art 52(4) EPC specifically, should be construed narrowly follows by applying the provisions of Arts 31 and 32 of the Vienna Convention, discussed in Section 2 above. The object and purpose of the EPC are encapsulated in Art 52(1) EPC, which provides that European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. Any provisions of the EPC which prevent this object and purpose being attained in certain technical areas must be construed narrowly if the object and purpose of the EPC are not to be compromised.

(21) To give an example of national practice, the narrow construction of exclusion clauses is also adopted in UK patent law, which has followed G5/83:

> **The Manual of Patent Practice Edition 5, The Patent Office, 2003**
> 1.08... ...it is a canon of legal construction that exceptions should be construed narrowly.
>
> **Terrell on the Law of Patents, 15th Edition, 2000**
> 2.15 The exclusion [corresponding to Art 52(4) EPC]...covers...methods of diagnosis. It is an exclusion which should be narrowly interpreted[8] but the dividing line between what is and what is not an excluded method has troubled the EPO on a number of occasions as it has, to a lesser extent, the courts of this country.

(22) For the above reasons, the Enlarged Board should continue to adopt a narrow interpretation to the exclusions from patentability embodied in the EPC generally, and to Art 54(2) EPC in particular.

4.2 Socio-Ethical Considerations

4.2.1 The Need to Stimulate Innovation

(23) The purpose of any patent system can usefully be summarised as follows:

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[8] G5/83 is here cited as authority.

> 2.3 The overall goals of the patent system are to stimulate innovation for the public good and to reward people for useful new inventions. The patent system aims to achieve this by allowing inventors exclusive rights for a limited period to exploit their inventions, while at the same time promoting competition and innovation by ensuring that such inventions are fully disclosed to the public. The system is intended to balance the interests of the public with those of the inventors. ...[9]

(24) The stimulation of innovation, then, is a primary purpose of the patent system. Because innovation will always be more costly than imitation, it is important for the innovators to have some kind of defence against the imitators. This applies particularly where:

a. The investment needed to achieve innovation is high (as with complex technology); and

b. There is a moral imperative to innovate (as in matters relating to healthcare).

(25) Both these considerations apply in the field of medical diagnosis. The equipment needed for certain diagnostic procedures is complex. Examples include magnetic resonance imaging (MRI), computed tomography (CT) and X-ray procedures. Research and development of new equipment useful in these fields is costly and time-consuming, yet society wishes that advancements in medical diagnosis continue. Accurate diagnosis not only enables effective and timely medical intervention if required, thereby improving a patient's quality of life, prognosis and, in particular cases, life expectancy, but also enables health resources, whether privately or publicly funded, to be better matched to actual clinical requirements. Businesses (including the medical diagnostics business of Amersham) have developed to fulfil this need for improved diagnostic procedures. Like any other technology-based business, these businesses need the protections afforded by the patent system in order to shelter the considerable investments made and allow a prospect of a commercial return. If the system is working well, this establishes a 'virtuous circle' of innovation whereby a proportion of the profits of one generation of innovation get ploughed back into researching and developing the next generation, to the benefit both of society and the investors who put up the money in the first place.

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[9] "The Ethics of Patenting DNA – A Discussion Paper", Nuffield Council on Bioethics, 2003

If patent protection is unavailable, investment is less likely to be made and innovation is less likely to result, so the virtuous circle is broken.

(26) In the context of novel and inventive items of equipment useful in diagnostic methods, patent protection is available for the equipment itself. This helps stimulate innovation in developing new equipment. But what about stimulating innovation in the use of existing equipment in new and improved ways?

(27) In the parallel field of medically and diagnostically useful compounds, whether chemical or biological, innovation in new therapeutic and diagnostic agents is stimulated by the availability of patent protection on compounds *per se*. But Art 52(4) EPC excludes from patentability uses of known compounds in this field. In the early years of the EPC, it was a legitimate concern that innovation in new uses of existing therapeutic and diagnostic agents was not being properly stimulated. (Arguably, society should place a premium on such endeavours, for there is much to be said for more fully exploring the properties of existing compounds, for example those whose toxicology had already been investigated.) All that was present in the EPC was the availability, by virtue of Art 54(5) EPC, of patent protection for medical and diagnostic uses of compounds which had never been proposed for use in such methods. This was the genesis of first medical use claims[10].

(28) The situation was much improved by the availability of second medical use claims as specifically sanctioned by the Enlarged Board in **G5/83**. A measure of protection was thereby to be had for protecting the *industrial aspects* of a second medical or diagnostic use of an existing therapeutic or diagnostic agent. The physician's freedom (such as it is – see Section 4.2.2 below) was not encroached upon.

(29) This development of protection for second (and subsequent) medical uses has found sufficient favour to be incorporated and (it is submitted) improved upon in the Basic Proposal for Revision to the EPC, according to which new Art 54(4) would read:

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[10] By definition, and by Art 54(5) EPC, first medical use claims are not available when a compound has previously been disclosed for a medical purpose – those very compounds which, it is argued in the text, pharmaceutical and diagnostic companies should be encouraged to research further.

> (4) Where the subject-matter of the invention is a substance or composition for use in a method referred to in Article 53(c), the substance or composition shall, without prejudice to paragraphs 2 and 3, be deemed to be new, provided that that use is not comprised in the state of the art.

(30) Unfortunately, while the prospects for protecting innovation, and therefore encouraging investment, in the field of second medical and diagnostic uses of known *compounds* has been improving, there has been no comparable improvement in the field of second medical and diagnostic uses of known *equipment*. It is not believed that there is any valid basis for drawing a moral distinction between a compound and a piece of apparatus. The inventor who develops, with much ingenuity and expense, a novel and inventive way of using an existing piece of equipment in diagnosis is, on the face of it, left without the prospect of patent protection. If such advances are left without protection, investment and future innovation will dwindle. What investor, when faced with the prospect of the free imitation of the innovative fruits of his investment and the consequence of a slight or non-existent return, will invest again? No law forces investors to plough money into diagnostics research and development. If it is commercially unattractive, it will not happen, save to the very limited extent funded by governments, hospitals and universities.

(31) This unfortunate state of affairs is to a slight extent ameliorated by the approach taken to the operation of the exclusion embodied in Art 52(4) EPC by the Technical Board in **T385/86**. By construing the exclusion narrowly, innovators working in the medical diagnostics field are afforded some degree of patent protection, and are thereby encouraged to invest and innovate in relation to existing equipment as well as to develop more radical diagnostic methods based on new equipment. However, the Technical Board in **T964/99** would remove even this degree of protection; if followed, this approach will lead to a diminution in investment in this important field of research[11], for the reasons outlined above.

(32) The narrow construction of Art 52(4) EPC favoured in T385/86, which it is submitted is soundly based in law, can therefore readily be justified in socio-ethical terms.

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[11] At least in Europe. It may be that investment, and jobs, will move elsewhere to a more favourable patent climate.

4.2.2 Fettering the Physician?

(33) Discussions of Art 52(4) EPC frequently point to the apparent justification of the exclusion as being to avoid inhibiting the medical practitioner. For example, T964/99 says:

> 3.1 ... The policy behind the exclusion of such methods is clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents (cf. T 116/85 (OJ EPO 1989, 13), point 3.7 of the reasons.)

(34) However, this justification does not withstand scrutiny. Notice that it is only methods themselves that are prohibited from patentability, not material (whether compounds or equipment) that is to be used in such a method. If the policy truly was to ensure that no physician (for example) could be sued for patent infringement, then *everything that a physician might use in his practice would have to be excluded from patentability*. No pharmaceutical agents, no diagnostic agents and no diagnostic equipment would be patentable (and the damage to society would be immense). This is clearly not the policy. It is somewhat difficult to establish just what the policy is. At the very least, it is confused. Early deliberations recorded in the preparatory works to the EPC (*e.g.* 6498/IV/64-E, pages 13-15 and 11821/IV/64-E, page 3) suggest that there was initially no unanimity on the question of whether pharmaceutical *products* should enjoy patent protection to the same extent as other compounds, and Art 52(4) EPC seems ultimately to have its origins in an uneasy compromise resolution to that debate. Art 52(4) EPC is therefore grounded in political reality rather than policy.

(35) In any event, it is submitted that the objective of protecting a medical professional from being "inhibited" by patents can be better attained by other legal means. Indeed, the more logical place for such protection is in legislation dealing with *patent infringement* as opposed to *patentability*. Some jurisdictions have enacted just such provisions. For example, in the United States, 35 USC §287(c)(1) provides:

> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281 [remedy for infringement], 283 [injunction], 284 [damages], and 285

> [attorney fees] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity [explanatory notes added].

And in Europe those states whose domestic laws are in line with the Community Patent Convention have provisions corresponding to Art 27(c) CPC, which provides a limited exception to patent infringement for pharmacists in the following terms[12]:

> ***Article 27***
> **Limitation of the effects of the Community patent**
>
> The rights conferred by a Community patent shall not extend to:
>
> (c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription nor acts concerning the medicine so prepared.

(36) So it cannot be the case that the policy underlying Art 52(4) EPC is in practical terms to prevent medical practitioners being inhibited. This policy cannot therefore be used to justify a broad interpretation of Art 52(4) EPC.

4.2.3 Business Reality

(37) Drawing the above two points together, patents are needed to protect industrial aspects of a diagnostic method, not the diagnosis itself. Commercial suppliers of agents or equipment for use in diagnostic methods would not be interested in suing clinicians (who after all are the customers -- hence any such action would make no business sense). Such patents instead are used to gain an advantage over other commercial (*i.e.* industrial) suppliers of such equipment/agents, and such commercial/industrial entities would be the object of any infringement

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[12] Preparatory document 6498/IV/64-E, pages 14-15, records that an early meeting of the Patents Working Party wished to incorporate this provision in the EPC, even though the EPC is concerned with patent procurement, not enforcement:

> After some discussion, the Working Party decided to provide that prescriptions prepared by a pharmacist on a doctor's instructions would not constitute infringement if the pharmacist's preparation was the same as a medicament protected by a patent.
>
> The Working Party thought that such a provision could be included in the convention. It felt that while its practical scope was quite small, its psychological impact was considerable. Such a provision recognised that principle of freedom to exercise the medical profession.

This shows early recognition that such freedoms were better legislated for at the point of patent infringement, as opposed to removing areas of technology form eligibility for patent protection at all.

action. This is very much the reality of the situation. Only if the clinician sought to get involved in commercial supply, as opposed to the needs of an individual patient, could such action be contemplated.

5 THE SCOPE OF ART 52(4) EPC

(38) Art 52(4) EPC does not exclude from patentability all diagnostic methods. Only those practised on the human or animal body are excluded. So a method may escape the exclusion clause *either* by not being a diagnostic method at all *or* by being a diagnostic method but one that is not "practised on the human or animal body".

(39) The points that need to be construed in relation to Art 52(4) EPC are:

a. What is a diagnostic method?

   i. A fully formed complete diagnostic method or a method usable in diagnosis?

   ii. Does a physician have to be present or to have responsibility?

b. When is a diagnostic method practised *on* the body?

5.1 Diagnostic Method or a Method Usable in Diagnosis?

(40) The Board in **T385/86** construed a diagnostic method narrowly, *i.e.* one whose results immediately made it possible to decide on a particular course of medical treatment (¶ 3.2). The Board went on to say:

> Methods providing only interim results are thus not diagnostic methods in the meaning of Article 52(4), first sentence, even if they can be utilised in making a diagnosis. T385/86 ¶3.2.

(41) Taking a contrary position, the Board in **T964/99** acknowledged at ¶3.5 that this line of reasoning equates the meaning of the expression "diagnostic methods practised on the human or animal body" in Article 52(4) EPC with the conventional meaning of the term "diagnosis". This in itself is of course a sound

reason why the analysis in T385/86 should be followed[13]. But the T969/99 Board did not follow the Board in T385/86. In diverging, the T964/99 Board said:

> ... a strict adoption of the principles set out in T 385/86 would lead to the conclusion that typical diagnostic procedures practised on the human body, like percussion, auscultation or palpation could, in principle, be patentable because they do not constitute a complete diagnosis and certainly do not fall within the further medical categories of surgery and therapy referred to in Article 52(4) EPC. However, the Board considers that it would go against the spirit of Article 52(4) EPC to interpret its provisions in such a way that "manual procedures" of physical examination essential for making a diagnosis and executed by a medical practitioner would not constitute an exception to patentability.

(42) Two points arise. First, an assessment of its "spirit" is not the appropriate way to construe Art 52(4) EPC. In accordance with **G5/83** ¶5, Art 52(4) EPC must be construed as required by the Vienna Convention in the light of *the object and purpose of the EPC* (see paragraph (9) above). This larger purpose must be taken into account, and as explained in paragraph (20) above is encapsulated in Art 52(1) EPC, which provides that European patents *shall be granted* for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. The approach of the Board in T385/86 is entirely in line with the Enlarged Board's instructions in G5/83, whereas the approach of the Board in T964/99 is not.

(43) Secondly, the answer to the T964/99 Board's concern about the patenting of procedures like percussion, auscultation and palpation is to be found in their own characterisation of them as "manual procedures". If they are truly manual, then they are not susceptible of industrial application and are excluded from patentability by Arts 52(1)/57 EPC (without needing to resort to any legal fiction). On the other hand, if someone should invent some sophisticated automated apparatus for performing, say, percussion, there is no good reason why either it or its use should not be patented if novel and inventive. In fact, both the legal and socio-ethical reasoning of Section 4 above shows why they *should* be patentable.

(44) The Board in T964/99 is concerned in ¶3.6 that T385/86 sets a different standard for methods of diagnosis from the case law (exemplified by T35/99 and

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[13] The Vienna Convention mandates that the terms of the treaty shall be given their ordinary meaning in their context; see paragraph (9).

T82/93) relating to methods of surgery or therapy "the latter being excluded from patent protection if they comprise only a single step of a surgical or therapeutic nature". To this we make three points:

a. In T35/99 at ¶3, the then competent Board themselves provided a distinction between methods of surgery and diagnosis: "surgery", they said, "defines the nature of the treatment rather than its purpose". This contrasts with diagnosis, which defines the purpose of the procedure rather than its nature.

b. More generally, there is no reason why the Art 52(4) EPC exclusions from patentability relating to surgery, therapy and diagnosis should all be construed similarly. Aside from the above point about surgery defining the nature of the treatment, which exemplifies some of the difference, the very wording of Art 52(4) EPC is different for diagnostics: it is only diagnostic methods *practised on the human or animal body* which are excluded.

c. And thirdly, we believe that the legal and socio-ethical reasoning of Section 4 above applies equally to other medical methods, and so if they are to be construed similarly then *all* the methods referred to in Art 52(4) EPC should be construed narrowly. The approach taken in T385/86 is to be preferred for this reason.

(45) If further justification were needed, a practical reason for preferring the approach in T385/86 is that it encourages applicants to give a full and undisguised disclosure of the invention. If the approach in T964/99 were followed, applicants would be motivated to disguise the true nature of their invention.

5.2 Physician's Presence or Responsibility

(46) We believe that the presence or responsibility of a physician should not be decisive for an assessment of patentability. The presence or absence of a particular health professional, and the nature of the ultimately responsible person, will depend on many factors, including:

- Country-specific norms and traditions (which vary even within the EPC contracting states)
- The continuing development of medical technology
- The adaptation of the respective roles of medical personnel to changing circumstances or new approaches to healthcare management (or political interference)
- Increasing automation of diagnostic procedures
- The increased availability of over-the-counter (OTC) diagnostics, in whose application no medical personnel are involved.

(47) When considered in conjunction with our view that the avoidance of fettering a physician's choice of actions cannot constitute a sound policy underlying Art 52(4) EPC (see Section 4.2.2 above), we see no reason why these almost arbitrary factors should have a decisive influence on patentability, particularly when Art 52(4) EPC itself makes no reference to the person carrying out the diagnostic method.

(48) If, however, the Enlarged Board does not follow this view, we believe that the view articulated in T385/86 at §3.5 is the next most coherent. According to this view, the ability of the method to be practised by a technician[14] characterises the procedure as a technical method which might be useful in diagnosis rather than as a diagnostic method.

5.3 Practised on the Body

(49) Art 52(4) EPC does not exclude the patentability of all diagnostic methods. It only excludes the patentability of diagnostic methods practised on the human or animal body. The preparatory papers to the EPC show that this rider was not in the original proposal, but was introduced during deliberations (see BR/177 e/72, ¶9c).

(50) In view of the legal and socio-ethical considerations that we have discussed in Section 4 above, we urge that the words "practised on the human or

[14] Or indeed patients themselves, as with OTC diagnostics

animal body" be interpreted to give a narrow effect to the exclusion. A properly narrow effect arises as follows.

(51) First, the preposition "on" must be given its full weight. The wording could have used some less precise construction such as "in relation to" or "with respect to", but did not. It used the simple and direct word "on", which generally implies physical contact with the body. The Board in T385/86 did not consider that the NMR procedure then under consideration was practised "on" the body, and the Board in T964/99 agreed that:

> 6.2... As a matter of fact, none of the methods judged in the above decisions [including T385/86] comprises a step which would have to be attributed to basic medical activities exercised on the human or animal body.

In respect of this particular point, therefore, there is no conflict between T385/86 and T964/99.

(52) Secondly, for the exclusion to operate, the entirety of the diagnostic method must be practised *on* the body, which at the least requires the patient's presence. The way in which this point is articulated in §4 of the reasoning in T385/86 is fully consistent with the analysis we present in Section 4 above, and we urge the adoption of this reasoning by the Enlarged Board.

6 QUESTIONS REFERRED BY THE PRESIDENT

(53) Based on the reasoning set out above, we have suggestions for how the specific questions referred by the President to the Enlarged Board should be answered. We set out below the questions and our suggested answers to them.

(54) First, the President asked:

> 1(a) Are "diagnostic methods practiced 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, ie 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), or

> 1(b) 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**?

(55) We urge the Enlarged Board to answer **question 1(a) in the affirmative** and **question 1(b) in the negative**.

(56) Secondly, the President asked:

> 2. If the answer to 1(b) 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?

(57) If, as we urge, question 1(b) is answered in the negative, this question does not arise. In fact, the very difficulties encountered when trying to answer this question indicate that question 1(b) *should* be answered in the negative. However, if question 1(b) is answered in the affirmative, we urge the Enlarged Board to answer **question 2 in the affirmative**. As to the criteria by which this should be assessed, we urge that the applicant/patentee in any given case be permitted to show whether the claimed method could be used in something other than a diagnostic method as excluded by Art 52(4) EPC. The content of the patent or application should be taken into consideration but should not in itself be determinative, since a claim may validly cover matter not disclosed in the application or patent.

(58) Thirdly, the President asked:

> 3(a) 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)?
>
> 3(b) 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?

(59) We urge the Enlarged Board to hold that the presence or participation of a physician is not decisive for the question of whether a claimed method is a diagnostic method. Therefore, we urge that **the answer to each of questions 3(a)(i), (3)(a)(ii) and 3(a)(iii) is "not necessarily"**. If the three questions of 3(a) are answered in this way, question 3(b) does not arise. But if the Enlarged Board is of the opinion that the participation of a physician is decisive, we urge that **the answer to question 3(b) is that the physician has to participate in all procedural steps**; the alternative would imply a broadening of the scope of the exclusion of Art 52(4) EPC which we do not believe is warranted for the reasons we have given.

(60) Fourthly, the President asked:

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

(61) We believe, with respect, that the President is here conflating the two requirements for the exclusion. To be excluded by the relevant portions of Art 52(4) EPC, a method must be a diagnostic method. But that is not enough: to be excluded, the method must be one of those particular types of diagnostic method that is practised on the human or animal body. This must be a subsequent enquiry, which only need be addressed if the method is a diagnostic method. Whether the method is or is not practised on the body does not make the method more or less diagnostic: that is to confuse the two issues. This can be seen by considering the case of a *prognostic* method practised on the human or animal body. Such a method is not excluded from patentability under Art 52(4) EPC because it is not a diagnostic method.

(62) Having said that, we urge the Enlarged Board to hold that **the answer to question 4 is that the requirement "practised on the human or animal body" means that the procedural steps take place in direct contact with the human or animal body** for the reasons we have discussed above. A method should not be excluded if it is carried out on a sample extracted from the human body (*e.g.* a blood sample). In fact, we question whether it is open to the Enlarged Board to express any

other view on this point as T385/86 and T964/99 are not in conflict on this point (see Section 5.3 above).

(63) We would be pleased to provide further elaboration or clarification of our views if the Enlarged Board wishes.

A. G Sheard
Authorised Representative

31 August 2004