

Philips Intellectual Property & Standards

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P.O. Box 220, 5600 AE Eindhoven, The Netherlands

FACSIMILE MESSAGE

European Patent Office
The Enlarged Board of Appeal
Erhardtstrasse 27
80331 MÜNCHEN
Germany

Tel: +31 40 27 43381
Fax: +31 40 27 43489
E-mail:
julius.cohen@philips.com

CONFIRMATION COPY

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Re: G01/04 'Diagnostic methods'

The referral G01/04 concerns the interpretation of the concept of 'Diagnostic Methods' in relation to the exclusion from patentability of methods of diagnosis pursuant to Art 52(4) EPC. We would like to take the opportunity to present observations on this case to the Enlarged Board of Appeal, in accordance with Art 11b of the Rules of Procedure of the Enlarged Board of Appeal.

Introduction

In this submission we will address the following issues. In our view there is a need among the IPR community, i.e. applicants, patent proprietors, opponents as well as the public and industry at large for legal certainty as to what the actual scope of the exclusion under Art 52(4) EPC is. We will explain that the exclusion principle pursuant to Art 52(4) EPC needs a clear and stable delimitation in the interest of the public at large as well as applicants, viz. the innovative industry in the field of healthcare. In fact, the definition of the excluded scope should hold over a considerable period of time and should also be clearly defined.

It is our view that the involvement of the medical practitioner into a definition of the concept of "diagnostic method" will lead to a dynamically changing definition of the scope of the exclusion.

We feel that answering the questions as formulated by the President in the referral at issue do not appear to completely meet the issue of stability over time and uniformity over the territory. Accordingly, we see a need to respond to the Questions referred by the President in a differentiated manner.



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Issues to be addressed by the Enlarged Board of Appeal in the referral G01/04 **Stability in time**

The scope of exclusion pursuant to Art 52(4) EPC should remain stable in time, i.e. applicable over e.g. at least a patent term. Notably, subject matter that is considered not excluded from patentability at some point in time, in particular at the date of grant of a European patent pursuant to Art 97 EPC, should not become considered excluded from patentability at a later instant. Such instability makes the validity of a European patent dependent on the instant when the validity is considered. It is noted at this point that opinions may change and also the view of the law may change. The Enlarged Board of Appeal have also recognised this in the decision G01/03 where it notes that because views may evaluate, disclaimers are an acceptable solution needed to enable the applicant to react to changes in the interpretation of excluded areas. However, in the interest of legal certainty it is well worth the effort to provide a definition of the scope of the exclusion that holds for a considerable period of time.

Further, such instability appears to be in conflict with the principle that patents should inspire technological development. Namely, further developments that are inspired by patented subject matter may turn out to have become excluded, while the earlier basic idea was open for patent protection. It seems unfair to the inventors who further developed that basic idea that they might not be entitled to the same protection as is available for the basic idea, only because the improvement was generated at a later date. To elaborate this point we present the following example.

Example: A method for examining the composition of blood in vivo by way of infrared spectroscopy. In this method there is no need to extract blood from the body, but a spectroscopic analysis is directly performed on blood within e.g. a blood vessel closely under the skin surface. Under a narrow interpretation of the exclusion under Art 52(4) EPC this method may be considered patentable as a technical method of spectroscopy. Subsequently an invention can be made for example pertaining to a particular optical filtering method especially set up to improve the spectroscopy of the earlier invention. When meanwhile the interpretation of the exclusion under Art 52(4) EPC has widened, it may be the case that the subsequent invention is excluded from patentability, while the European patent concerning the basic invention remains granted.

In practice, the subsequent implementation may be commercially equally important as the invention on the basic insight. In this situation the broadening of the scope of the exclusion from patentability may lead the inventor of the subsequent inventions on implementations to keep their inventions secret. Hence, widening of the scope of exclusion may counteract the function of the patent system to stimulate technology. Narrowing the

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scope of exclusion seems unfair to inventors achieving breakthrough inventions and may lead to these breakthroughs kept secret and hence not being distributed widely.

Further, uncertainty as to the scope of exclusion under Art 52(4) EPC also appears to be in conflict with the principle of legitimate expectations based on which applicants decide to file European patent applications. As decisions of the Enlarged Board of Appeal are recognised as a source from which legitimate expectations are derived (T725/95), we call upon the Enlarged Board of Appeal in the present referral to provide a clear and stable interpretation of the scope of exclusion under Art 52(4) EPC.

The definition of the scope of the excluded subject matter should be also applicable to future technologies. Notably, currently under development there are molecular diagnostics technologies that aim at distinguishing risk of developing pathologies, rather than establishing if a body actually is in a pathological state. Accordingly, there is a foreseeable need to establish whether detection of a degree of predisposition for developing a pathology is to be considered equivalent to establishing an actual pathology.

An affirmative response to Question 1a (is the scope of Art 52(4) limited to methods that include the deductive medical decision phase?) and to some degree to Question 3a(iii) (does the scope of Art 52(4) extend to methods that include steps that may be practised by medical or technical support staff, the patient himself or an automated system?) referred by the President will provide a temporally stable interpretation. However, such a quite narrow interpretation may not treat all medical methods referred to in Art 52(4) EPC on an equal footing. Moreover, such a narrow interpretation provides for formally avoiding the exclusion by mere wording of the claims, rendering Art 52(4) without practical effect. Question 3(to what extent does the scope of Art 52(4) depend on the involvement of a medical practitioner?) of the Referral in its entirety pertains to the involvement of the medical practitioner which is discussed in detail further on. The involvement of the medical practitioner leads to a changing with time of the scope of the exclusion. Accordingly, an affirmative response to Question 3 does not solve the issue of a temporally stable definition. Further, an affirmative response to Question 3a(iii) calls for a different differentiator to indicate what is encompassed by diagnostic methods.

Clarity of the excluded scope

Clear indications are needed which indicate what subject matter is to be excluded from patentability. The issue of clarity is an important issue in several aspects of the EPC. In the interpretation of the EPC there are several aspects where the clarity of the delimitation between protected subject matter and subject matter that is free from patent protection is an important issue. As illustrations of the aspects of clarity, we refer to Art 84 EPC (clarity of subject matter of the claims), the decision G02/98 (clarity of subject matter entitled to priority) and the decision G01/03 (clarity of disclaimers).

A clear definition of the scope of the exclusion under Art 52(4) EPC may serve to inspire the relevant courts in the contracting states to a uniform interpretation of the exclusion under Art 52(4) EPC when deciding on validity issues of European patents pursuant to Art 138(1) a)

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EPC. As will be elaborated in more detail below, the decision T964/99 does not provide a clear definition of what is considered a diagnostic method to be excluded from patentability.

In the decision T964/99 the Board sets out to define the boundary of the subject matter that is excluded from patentability under Art 52(4) EPC in terms of: 'Fundamental diagnostic activity, Essentially diagnostic measure, Essential activity pertaining to diagnosis or Elementary diagnostic activity'. From the context of T964/99 it would appear that the Board tries to construe a specific class of subject matters that fall within the exclusion pursuant to Art 52(4) EPC. That is, to limit the exclusion to a definite category of subject matter. However, in the decision T964/99 the Board is unclear in that different wordings are employed to indicate what is presumably the same category of (to be excluded) subject matter; and in T964/99 there is no clear definition of what exactly is meant by the terminology 'Fundamental diagnostic activity, Essentially diagnostic measure, Essential activity pertaining to diagnosis or Elementary diagnostic activity'. No other examples besides the very case at issue (extraction of a to be examined body sample by iontophoretic measures from a human body) were given but only exemptions from this rule were discussed (namely NMR methods that should still be allowed as they are to be regarded as purely technical methods). Therefore, what is meant by 'Fundamental diagnostic activity, Essentially diagnostic measure, Essential activity pertaining to diagnosis or Elementary diagnostic activity' is unclear..

The issue of clarity, is addressed in Questions 1a, 2 (is the scope of Art 52(4) limited to methods usable only for diagnostic purposes?) and Question 4 (does the scope of Art 52(4) extend to methods in which at least one step is practised directly on the body?). However, it also appears that a detailed reasoning and elaborate response to these questions is required to resolve the issue of clarity.

In view of the above reasoning, Question 1a should be responded to affirmatively, as this leads to clear delimitation of the excluded scope. However that delimitation may be ineffective because the intended exclusion could be avoided any avoiding to explicitly including the deductive medical decision step while retaining the steps leading up to enabling the deductive medical decision.

We tend to negatively respond to Question 1b(does a single step relating to diagnosis confer diagnostic nature onto the claimed method as a whole?). Technical method steps may be of (indirect) value for a diagnosis. Consequently an affirmative response to Question 1b excludes from patentability technical methods that solve a technical problem on the count that they may be ultimately of value for a diagnosis, This would be contrary to a narrow interpretation of the exception from patentability in Art 52(4) EPC. In T964/99 (rn6.2) it is in our view correctly held that the (internal) operation of a technical device may be regarded as patentable [...]even if its results maybe evaluated for diagnostic purposes.

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Compliance with the rationale behind Art 52(4) EPC

How to interpret the scope of the exclusion pursuant to Art 52(4) and how to consider the extent of involvement of the medical practitioner is critical is to be done within the context of the rationale behind Art 52(4) EPC. This rationale also implies that all medical methods should be treated on an equal footing when assessing whether the exclusion under Art 52(4) EPC applies.

The purpose of Art 52(4) EPC is to limit exclusive rights conveyed by European patents in their applicability to diagnostic methods. This exclusion from patentability realises that for the public, notably patients, the availability of medical methods is to a certain degree not hindered by any patent rights. Medical practitioners accordingly should be concerned too much with (European) patents when providing direct care to their patients. As products, in particular substances for use in diagnostic methods and also (the use of) technical apparatus is open to patentability, the intention of Art 52(4) is not to segregate the field of medical care from the patent system; rather to render direct health care to some degree insensible to patents.

In our view this principle can only be implemented to its full extent, when the scope of the exclusion is independent of any particular medical diagnostic modality (i.e. techniques to non-destructively image the interior of a living body, such as MRI, CT, X-ray imaging, PET, SPECT, Ultrasound imaging, Cardiac monitoring etc.) that is employed in a medical diagnostic method. In the event that different criteria apply to respective modalities, the existence of patents influences the choice which method to employ in a particular pathology. Then to the patient/person to be examined in the context of receiving healthcare not all methods are available free from patent protection. In this respect it is observed that the scope of the exclusion should be governed by equal principles on the one hand for all categories of methods listed in Art 52(4) EPC: surgery, therapy and diagnosis and on the other hand all medical (imaging) modalities should be handled on an equal footing.

Examples: CT methods are considered to be excluded due to being invasive (surgical) as some examining divisions allege the destructive nature of X-rays. On the other hand, neither the Guidelines (of December 2003) nor any decision has ever disallowed any X-ray method in which simply physical data is gathered from the living human or animal body. Furthermore, the tendency to exclude even CT methods that only deal with the way of arranging the read-out electronics of the X-ray detector have no counterpart in radiographic X-ray methods. The only difference being a potential difference in the mean X-ray energy used in CT and radiography.

The issue to treat all medically related methods on equal footing, is related to Question 2 of the Presidents referral in that the criteria to assess the diagnostic character should pertain broadly to medically related methods. An appropriate response to Question 2 we feel should clarify the concepts of 'Of value for diagnosis' and 'Fundamental diagnostic activity etc.'

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Also Question 4 pertains to this issue in that the criterion that one step of diagnostic character in a claimed method being decisive is analogue to the way surgical and therapeutic methods are treated (cf. T820/92).

Involvement of the medical practitioner

Application of the criterion of involvement of the medical practitioner does not appear to lead to a workable delimitation of the excluded subject matter pursuant to Art 52(4) EPC. Notably, the requirement of involving medical practitioners in a method may change in time. As technology progresses, in the healthcare industry opinions may change as to whether a particular method needs to be applied by a medical practitioner having particular skills. Consequently, subject matter that falls within the exclusion on the ground that the involvement of a medical practitioner is required at some point in time, may turn out later to be beyond the exclusion when due to changed opinions and technological developments, the medical practitioner is not required to be involved. Accordingly, basic inventions that open up a field may be excluded from patentability, whereas later inventions that build further on the basic insight may be patentable. Or, technological progress may reveal higher risks, e.g. due to side effects found later, which may lead to a recognition of a more intense involvement of the medical practitioner. Moreover, these requirements and the way they are implemented vary among EPC Contracting States. Hence, the involvement of a medical practitioner as a requirement to define the excluded subject matter appears to be at variance with the unity of the European Patent pursuant to Art 118 EPC.

Examples: A method where the medical practitioner is required to constantly monitor the possible anaphylactic reaction of patient that got injected a certain contrast agent was excluded (T 655/92). Several aspects came together: injection of contrast agent (surgical step; at least implicitly required), harmful side effects of the contrast agent, requirement of the presence of a medical practitioner to monitor the patient. A method of acquiring CT images from a patient was excluded (in the granting process) as the examining division alleged that a medical practitioner was needed. As a matter of fact, a medical practitioner is often not needed to attend during the CT acquisition (as there is no harmful side effect that needs monitoring during the acquisition); a medical practitioner is usually only involved in the process to decide whether a CT acquisition should be made and the subsequent interpretation of the images. The latter shows that the examining divisions, due to lack of a clear definition, sometimes tend to a wide interpretation based on some isolated aspect derived from a single decision.

It is further noted that assessment of the involvement of the medical practitioner will in practice be difficult to assess during the examination of a European patent application. Information on the involvement of the medical practitioner is often not included in the documents making up the European patent application (Art 78 EPC).

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As a further remark, one might suggest to delimit the scope of exclusion to coincide with the scope of actions that are exclusively limited to medical practitioners on the basis of legislation to that effect. However, such legislation is mainly based on national law of the contracting states and appears to be at variance with the unitary nature of European patents (Art 118 EPC). For this reason also, implementation of such a delimitation may not be practical during examination of European patent applications by the Examining Divisions and Opposition Divisions and Boards of Appeal.

Besides, it seems inconsistent to exclude from patentability to exclude a method (e.g. to diagnose a patient's heart condition) in which the steps are performed by a medical practitioner, while patent protection is made available for the same method in which the same steps are performed by an automatic system (e.g. a automatic external defibrillator) and leading to the same result. As to Question 3 (in its entirety), we are of the opinion that assessing whether a claimed method falls within the exclusion pursuant to Art 52(4) EPC should not depend on the actual or organisational involvement of the medical practitioner. Adequate criteria have already been proposed in the Board of Appeal's decision T329/94, where the Board of Appeal holds that the purpose and inevitable effect of the feature under consideration are much more important(rn. 5).

Scope of the exclusion under Art 52(4)

The purpose of the patent system (in general and the European patent system in particular as implemented in the EPC) is to stimulate progress of technology by rewarding the inventors in order to allow a proper return-on-investment for their innovative efforts. Accordingly, society is expected to benefit from technological progress. The more subject matter is excluded from patentability, the less benefit society is expected to have from innovations. Hence, any exception to what is susceptible for patent protection is to be construed narrowly as such exceptions inherently jeopardise benefit to society through patent protection.

An operable definition of the subject matter of diagnostic nature that falls within the exclusion pursuant to Art 52(4) EPC in our view is to be based on the following criteria. The excluded subject matter should be limited to methods that involve one or more steps that need to be carried out in direct interaction with the human or animal body to be examined. The rationale behind this limitation is that investigations of data, such as samples of tissue or body fluid or image information, separate from the patient's body are generally considered as technical methods susceptible of patent protection. Typically, extra corporal laboratory tests would be patentable.

A further limitation of the excluded subject matter is whether the method as a whole enables to distinguish a particular pathology (or a narrow class of pathologies) from other (narrow classes of) pathologies and from the healthy state of the body under examination. That is, analysis of a sample or of image information of which in itself does not enable the distinction of a particular pathological or non-pathological state of the patient's body should be considered as a technical achievement and not within the exclusion of Art 52(4) EPC.



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Here the question is where the borderline lies between a method that delivers some physical data and a method that delivers (almost) a diagnosis derived from physical data. In other words, a method of which the result is in fact the entrance of a one way street leading with certainty to the conclusion as to which (if any) pathological state is to be distinguished from a method that only leads to a mere suspicion of a class of pathologies at issue. The rationale behind this limitation is that on the one hand the criterion 'of value for a diagnosis' as brought forward in T964/99, encompasses methods that involve purely technical considerations, but in an indirect way may lead to an advantage in establishing a diagnosis and on the other hand the strict interpretation used in the Board of Appeal's decision T385/86 does seem to render the exclusion under Art 52(4) EPC without effect.

Examples: On the one hand a method to establish by way of a rule based approach (fuzzy logic) from a plurality of data and symptoms a patient's heart condition with a distinction of false positives is considered a diagnostic method that is excluded from patentability. On the other hand a 3D imaging method of the patient's coronary arteries with a correction step to compensate for the motion of the heart in itself only leads to a mere suspicion (but founded) that the blood supply may be deficient. The latter method only leads to an image – a representation of physical data non-destructively extracted from the living human body – and the invention resides in the way the data is handled.

In a discussion of Questions 1a, 2 and 4 it is relevant to delimit the scope of the exclusion in view of the nature of the invention as claimed as a whole and on the basis of technical considerations with regard to the problem solved by the invention. However, a simple yes or no will not suffice, as is also apparent from the request to provide criteria in Question 2 (final sentence).

In relation to this suggestion it is observed that in practice reaching a diagnosis involves a complex procedure in which gathering and processing of data (samples, signals, measurements, images) is only one constituent of the diagnostic process. A measurement of a particular quantity, an image (series) of a particular type at best leads to a suspicion that the pathology is within one or a few broad classes of pathologies. An actual diagnosis is only reached when from the wide class of suspected pathologies one has narrowed down into a comparatively detailed (clinical) picture, which ascertains which distinct pathology is at issue. This process of narrowing down involves intelligent selection and monitoring of quantities or other observations. This process of differentiating among pathologies from broad classes is often named differential diagnosis. However, a combination of steps that only leads to partial information on the state of the body under examination is to be considered in most instances as a the technical operation of a technical device. Notably, a method that only provides an image in itself of the internal structure of the human or animal body very seldom leads in itself to a diagnosis in that one can conclude on a particular pathology. To the contrary, the image information often needs to be supplemented by clinical information and



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measurements of other physiological quantities to actually reach a diagnosis. The criterion 'of value for a diagnosis' as introduced in T964/99 is very broad and encompasses methods that are clearly technical.

Examples: A method to mount an MRI-system in an examination room to achieve the technical effect that the MRI system is electromagnetically isolated from the surroundings of the examination room may very well be considered as of value for a diagnosis but are in normal every day's consideration to be regarded as a technical operation (electromagnetically isolated mounting) of a technical device (an MRI-system comprising a magnet system with an RF system and a magnetic gradient system that include coils and electronic control).

Likewise, a method to calibrate a CCD-camera, which is a general technical problem, might be considered to be of value for diagnosis as e.g. images of the patient's skin taken with this camera may be used in a telemedicine exchange between a patient and a doctor.

The distinction between the technical operation of a technical device which is open for patent protection (T329/94, T964/99) and a diagnostic method excluded from patent protection should be made with the method as claimed as a whole and with regard to the problem solved by the invention. Methods that as a whole solve the general problem how to reach a situation from which a pathology can be ascertained, could fall within the exclusion from patentability. In contrast, methods that merely solve a technical problem although within the broader complex diagnostic process should be considered to be technical and susceptible of patent protection.

It is further noted that the exclusion as defined in the wording of Art 52(4) EPC is limited to methods 'applied to the body'. Question 4 addresses this issue, and in our view this Question should be responded to with regard to the claimed method as a whole. Only if direct interaction with the body makes a real difference whether the object of the invention is achieved should be regarded to fall within the exclusion. On one hand, when interaction with the body is only required to define the problem of the invention on the other hand interaction with the body may be required to solve the problem of the invention as a whole. For example, acquisition of data, such as image data, requires interaction with the body, but for the subsequent processing of these data the presence or absence of the body is irrelevant. Such data acquisition is to be regarded as operation of a technical device.

Examples: The acquisition of physical data from a human or animal body by use of an MRI or an X-ray device is usually allowed. The device interacts via electromagnetic waves with the patient. Does this mean that any method that analyses a heap of physical data acquired in a previous step, e.g. by means of a rule based approach (fuzzy logic), to derive a diagnostic result is not to be considered a diagnostic method in the sense of Art 52(4) EPC as the method was performed on the physical



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data but not on the human or animal body? A method to in vitro analyse the content of blood is allowed (as long as the blood is not reintroduced into the body from which it was taken – see Guidelines C-IV, 4.2.1). Such a method may yield a diagnostic outcome but is only performed on the blood sample and not on the human or animal body. A method that includes the step of (non-invasively) extracting a body sample (that is not planned to be reintroduced into the body) seems to be excluded (T 964/99). Where is the borderline between the explicit step of extraction and the implicit step of extraction?

Concluding remarks

We have found that, although responses to the set of Questions referred by the President will certainly add to the understanding of the delimitation of the exclusion from patentability pursuant to Art 52(4) EPC, a simple response to these Questions will not resolve all issues set out above. Accordingly, we feel that the Enlarged Board of Appeal should provide a clear guidelines to the interpretation and practical implementation of the scope of the exclusion by considering the issue raised in the Presidents Referral more broadly than only on the basis of the literal wording of the Questions. These guidelines and their implementation should be based on a thorough understanding of the rationale behind Art 52(4) EPC. A good understanding of the definition appears to require a clear indication on how the exclusion is based on the rationale behind Art 52(4) EPC.

In conclusion we feel that the Enlarged Board should set out to

Provide legal certainty to the public at large and in particular to the IPR community as to the scope of the exclusion pursuant to Art 52(4) EPC. This will be achieved by

- (i) Providing a clear definition of the scope of the exclusion, notably by clarifying the concepts of 'Of value for diagnosis' and 'Fundamental diagnostic activity etc.'
- (ii) Providing such definition that is stable in time and is applicable as far as reasonable foreseeable to future technologies.
- (iii) Consider to set forth the delimitation of the excluded scope on the basis of the claimed invention as a whole, taking into account the problem, the measures to solve the problem and the effects achieved by the claimed method as a whole. This especially applies to how to construe the provision 'applied to the body'.



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Glossary of our view of the responses to the Questions in the President's Referral

Question 1a concerns whether the scope of Art 52(4) is limited to methods that include the deductive medical decision phase. Question 1a should be responded to affirmatively, as this leads to clear delimitation of the excluded scope. However that delimitation may be ineffective because the intended exclusion could be avoided any avoiding to explicitly including the deductive medical decision step while retaining the steps leading up to enabling the deductive medical decision.

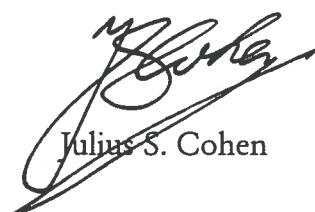
Question 1b concerns the issue whether a single step relating to diagnosis confers diagnostic nature onto the claimed method as a whole?). Question 1b we tend to negatively respond to. Technical method steps may be of (indirect) value for a diagnosis. Consequently an affirmative response to Question 1b excludes from patentability technical methods that solve a technical problem on the count that they may be ultimately of value for a diagnosis,.

Question 2 concerns whether the scope of Art 52(4) limited to methods usable only for diagnostic purposes? An appropriate response to Question 2 we feel should clarify the concepts of 'Of value for diagnosis' and 'Fundamental diagnostic activity etc.'

Question 3 concerns whether the scope of Art 52(4) depends on the person performing the method, in particular does the scope of Art 52(4) extend to methods that include steps that may be practised by medical or technical support staff, the patient himself or an automated system? An affirmative response to Question 3 does not solve the issue of a temporally stable definition , because the involvement of the medical practitioner leads to a changing with time of the scope of the exclusion.

Question 4 concerns whether the scope of Art 52(4) extend to methods in which at least one step is practised directly on the body?. As to Question 4 in our view the issue 'applied to the body' should be responded to with regard to the claimed method as a whole. Only if direct interaction with the body makes a real difference whether the object of the invention is achieved should be regarded to fall within the exclusion.

The professional representative,



Julius S. Cohen