

VEREENIGDE NEWS

International newsletter of VEREENIGDE

Dear Reader,

It is with great pleasure that I present to you the first issue of VEREENIGDE NEWS, a publication by which VEREENIGDE seeks to inform you regularly about recent developments regarding Dutch and European patent and trademark issues.

For some years now, our Dutch relations have periodically received issues of our Dutch newsletter "IE-mail" (IP is IE in Dutch), with general information about developments in our firm and information about miscellaneous IP topics. Generally, reactions to "IE-mail" have been very positive and this has led us to the idea of creating a similar publication for our relations outside The Netherlands.

The publication of the first issue of VEREENIGDE NEWS is one of the highlights of 2006, the year in which our firm celebrates its 90th anniversary. It was in 1916 that three small patent agencies decided to merge, joining forces under the new name of Vereenigde Octrooibureaux (literally: United Patent Agencies). Now, 90 years later, VEREENIGDE is the leading patent and trademark agency in The Netherlands, with 160 employees, including 35 patent attorneys and trainees, 7 trademark attorneys and 2 attorneys-at-law.

Another highlight is the recent launch of our new website (www.vereenigde.com), now still more informative and user-friendly. I invite you to visit our website and to share your opinion with us (click on "contact" and "comment on our website").

I hope that you appreciate these initiatives and that our newsletter will provide you with interesting and useful information on intellectual property.

Frans A. Dietz, Chairman



Photo: Stefan Mizee

Frans Dietz

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Decision of Enlarged Board of Appeal on diagnostic methods

By Kasper Haak

According to Article 52(4) of the European Patent Convention (EPC) diagnostic methods practised on the human or animal body are not regarded as inventions which are susceptible of industrial application within the meaning of Article 52(1) EPC. In the past, different interpretations of this article have been used in the European Patent Office (EPO). In the strictest interpretation, this article was held to forbid method claims that involved a step performed on the human or animal body for the purpose of diagnosis.

In practice, this made patent protection impossible for inventions wherein application to the human or animal body during a diagnostic procedure was necessary to distinguish from the prior art. On the other hand, in the most lenient interpretation, Article 52(4) was held to forbid only method claims that included a step of reaching a diagnosis. The Enlarged Board of appeal decision, which has final authority about interpretation of the EPC before the EPO, has now settled this point by siding with the more lenient interpretation.

The President of the EPO referred the point of law that arose from the contradicting Board of Appeal decisions T 385/86 and T 964/99 to the Enlarged Board of Appeal (G 1/04).

Referral to the Enlarged Board of Appeal T385/86 stated that the only diagnostic methods to be excluded from patent protection are those whose results immediately make it possible to decide on a particular course of medical treatment. In other words, methods providing only interim results are not diagnostic methods in the sense of Article 52(4) EPC, even if the results could

be used in making a diagnosis. The consequence of this interpretation of Article 52(4) EPC is that methods not containing all the steps involved in making a medical diagnosis would not be excluded from patentability (conclusion President).

In contrast, T 964/99 stated that the expression “diagnostic methods practised on the human or animal body” should not be considered to relate to methods containing all the steps involved in reaching a medical diagnosis. This Board considered that in accordance with the ordinary meaning to be given to the terms of the EPC-treaty in its context (good faith principle), Article 52(4) EPC is meant to exclude from patent protection all methods practised on the human or animal body which relate to diagnosis or which are of value for the purposes of diagnosis. Essentially all that is needed to justify exclusion under Article 52(4) EPC is that the claimed method comprises one step which serves diagnostic purposes or is related to diagnosis.

Ratio of exclusion of diagnostic methods The Enlarged Board of Appeal reminded that the exclusion from patentability of the above-mentioned methods under Article 52(4) EPC seems to be based on

socio-ethical and public health considerations. Medical and veterinary practitioners should be free to take the actions they consider suited to diagnose illnesses by means of investigative methods.

According to established jurisprudence, making a diagnosis as part of a medical treatment of humans or a veterinary treatment of animals for curative purposes includes at least four phases, viz.: (i) the examination phase involving the collection of data, (ii) the comparison of these data with standard values, (iii) the finding of any significant deviation, i.e. a symptom, during the comparison, and (iv) the attribution of the deviation to a particular clinical picture, i.e. the deductive medical or veterinary decision phase (diagnosis for curative purposes *stricto sensu*).

The Enlarged Board argued that the deductive decision, phase (iv), as a purely intellectual exercise (unless it is carried out by a device), cannot be regarded as an invention within the meaning of another article of the EPC (Article 52(1)). In order to be an invention in the sense of Article 52(1) EPC, the non-technical decision phase must necessarily be accompanied by preceding steps of a technical nature.

The Enlarged Board continued that according to Article 4(3) EPC, it is the general task of the EPO to grant European patents. Moreover, Article 52(1) EPC lays down the fundamental maxim of a general entitlement to patent protection to the effect that, as a matter of principle, a European patent is to be granted

for an invention which meets the requirements of that provision. It is true that there are exclusion clauses from patentability provided for in the EPC. It is also true that the frequently cited principle, according to which exclusion clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception.

However, the Enlarged Board of Appeal considers that the principle of a narrow interpretation of such exclusion clauses is to apply in respect of the scope of the exclusion from patentability under Article 52(4) EPC concerning diagnostic methods. The wording of Article 52(4) EPC does not relate to particular steps in such methods. Thus, the text of

the provision itself already gives an indication towards a narrow interpretation in the sense that, in order to be excluded from patentability, the method is to include all steps relating to it.

Further, it is difficult to define medical or veterinary practitioners on a European level for the sake of preventing them to be inhibited by patents in their diagnosis actions. From this it follows that, for reasons of legal certainty, which is of paramount importance, the European patent grant procedure may not be rendered dependent on the involvement of such practitioners: whether or not a medical or veterinary practitioner is involved in the method plays no role when deciding if the method is a diagnostic method in the sense of Article 52(4) EPC. Since a comprehensive protection of medical and veterinary practitioners may be achieved by other means if deemed necessary, the Enlarged Board is of the opinion that a narrow interpretation of the scope of the exclusion from patentability referred to above is therefore equitable. With regard to diagnostic methods involving method steps of a technical nature carried out by a device, such methods are in principle patentable if the technical method steps are not performed on the body. However, the Enlarged Board noted that recent developments in the field of diagnostics for curative purposes render these methods more and more complex and technically sophisticated, so that it is becoming increasingly difficult for medical or veterinary practitioners to have the means to



Photo: Remco Frank

carry them out. In this respect, they will hardly be hampered in their work by the existence of patents related to such methods.

Decision of the Enlarged Board

For a diagnostic method practised on the human or animal body to fall under the prohibition of Article 52(4) EPC, the claim must include features relating to:

- (i) the diagnosis for curative purposes *stricto sensu* representing the deductive medical or veterinary decision phase as a purely intellectual exercise,
- (ii) the preceding steps which are constitutive for making that diagnosis, and
- (iii) the specific interactions with the human or animal body which occur when carrying those out among these preceding steps which are of a technical nature.

Whether or not a method is a diagnostic method within the meaning of Article 52(4) EPC may depend neither on the participation of a medical or veterinary practitioner, by being present or by bearing the responsibility, nor on the fact that all method steps can also, or only, be practised by medical or technical support staff, the patient himself or herself or an automated system. Moreover, no distinction is to be made in this context between essential method steps having diagnostic character and non-essential method steps lacking it. In a diagnostic method under Article

52(4) EPC, the method steps of a technical nature belonging to the preceding steps which are constitutive for making the diagnosis for curative purposes *stricto sensu* must satisfy the criterion “practised on the human or animal body”.

Article 52(4) EPC does not require a specific type and intensity of interaction with the human or animal body. A preceding step of a technical nature thus satisfies the criterion “practised on the human or animal body” if its performance implies any interaction with the human or animal body, necessitating the presence of the latter.



The Enlarged Board opted for a formal test that allows the issue of exclusion from patentability under Article 52(4) EPC to be decided just by looking at the type of steps that the claim contains.



Consequences of the decision of the Enlarged Board In the decision, the Enlarged Board opted for a formal test that allows the issue of exclusion from patentability under Article 52(4) EPC to be decided just by looking at the type of steps that the claim contains. Several amici voiced concerns that such a formal approach would lead to a practice wherein Article 52(4) EPC could be flouted simply by deleting one type of step from a claim. The Enlarged Board played down such concerns, because it felt that EPO would force applicants to include such steps in method claims if they were essential to the invention (only to reject the claim as excluded under Article 52(4) EPC). It must therefore be expected that examiners will look very strictly whether applicants can be forced to include steps such as the diagnosis *stricto sensu* step and steps that interact with the human or animal

body in their method claims, by arguing that these steps are essential for the invention. Applicants should be prepared to have arguments why these steps are not essential for their invention. One way of arguing may be to formulate an object of the invention in terms of providing for a method to measure *physical or chemical properties*, instead of an object in terms of *diagnostic goals*. Needless to say, European patent applications, where possible, should avoid statements that a diagnosis step *stricto sensu* or a step that interacts with the human body is essential. Claims without all these steps should preferably be included already on filing. Moreover, claims to a device that provides automated diagnosis should be included if relevant, as such claims are not expected to be rejected under Article 52(4) EPC.

This leaves problems only for inventions wherein the diagnosis step *stricto sensu* by a human is an inseparable part of the invention. It is to be noted that Article 52(4) EPC also applies to exclusion from patentability of *surgical and therapeutic methods*.

Although not the subject of the present decision, it may be noted that with respect to methods of surgery or therapy, the Enlarged Board has endorsed the “single step” approach whereby a method claim falls under the prohibition of Article 52(4) EPC if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of the human or animal body by surgery or therapy. The Enlarged Board indicated that the restrictive interpretation of patent exemption for diagnostic methods does not amount to setting a different standard for diagnostic methods than that established for methods of surgery or therapy.

EPC2000 – An overview of the main changes

By Karen Thirlwell

In 2000, a diplomatic conference was held in Munich to revise the European Patent Convention (EPC) which was drafted in 1973 and has been in force ever since the EPO began. The result of this diplomatic conference is the European Patent Convention 2000 (EPC2000).

The aim of the revision of the EPC was to remedy weaknesses in the EPC 1973 and to respond to external developments including international patent law (for example TRIPs and the Patent Law Treaty (PLT)), the needs of users and deregulation. The aim of the revision was also to streamline European procedures with a view to providing flexibility to adapt to further developments. EPC2000 will enter into force on 13 December 2007 which is 2 years after ratification of EPC2000 by the 15th member state, which was Greece on 13 December 2005. Any member state which does not ratify by 13 December 2007 will cease to be a party to the EPC.

EPC2000 differs with respect to the present EPC1973 in various respects. EPC2000 has been streamlined by transferring many procedural details, such as time limits from the Convention (Articles) to the Implementing Regulations. This provides flexibility, since with EPC2000 procedural changes will be able to be decided by the EPO's administrative council rather than necessitating a diplomatic conference, which is the case with the EPC1973, which requires a diplomatic conference to amend the Articles of the Convention.

Main changes

A whistle stop tour of the main changes is now given:

i) New Procedures:

With respect to EPC1973, EPC2000 offers two new procedures: under new Article 105a, b, c, a patent proprietor may apply directly to the European Patent Office for limitation or revocation of a granted European patent. Further, under new Article 122a, a petition for review of Board of Appeal decisions may be filed. It is to be noted that such petitions may only be filed for fundamental procedural defects of criminal acts impacting on the decision. Further, such a petition will have no suspensive effect.



EPC2000 has been streamlined by transferring many procedural details, such as time limits from the Convention (Articles) to the Implementing Regulations.



ii) Remedies:

In EPC2000, the remedies available to parties to proceedings before the EPO have also been changed with respect to EPC1973. Further processing as set out in Article 121 EPC which currently exists as a remedy under EPC1973 having rather

limited applicability, in EPC2000 is provided as a more general remedy for failing to observe a time limit by payment of a fee within two months of a communication of failure to pay or noting loss of rights. The second remedy available under EPC1973, that of restitutio in integrum as set out in Article 122 EPC, has been narrowed down in its application in EPC2000. For example, restitutio in integrum is no longer available if further processing is available. Restitutio in integrum has however, been made available in EPC2000 for failure to file a subsequent application within the priority year if the applicant requests within two months of expiry of the priority year. This remedy is not available at all in EPC1973. It is to be noted that the conditions for a successful remedy using restitutio in integrum are the same as in EPC1973.

iii) Filing Requirements:

In EPC2000, the requirements for securing a date of filing have been amended. Under EPC2000, it will no longer be necessary to file a claim in order to secure a filing date. Further, a reference to a previously filed application may be used to replace the description and the

contact details of the applicant are sufficient to secure a filing date. With respect to the filing of European patent applications, under EPC2000 European applications may be filed in any language, claims may be late filed within two months of a communication from the EPO

informing the applicant that they are missing, it is not necessary to file a declaration of priority upon filing. Instead, the declaration of priority may be made or corrected within 16 months of the priority date. In a further relaxation with respect to current European practice, under EPC2000 missing description pages may be filed late without redating being necessary, provided they are completely contained within the priority document.

iv) Priority:

In EPC2000, the priority requirements have also been brought in line in accordance with TRIPs, so that priority will be recognized from WTO member states. Further a priority claim may be made or corrected within 16 months from the priority date. Further a translation of the priority document will be requested only if relevant to patentability.

v) Prior art:

A further main change is that intervening publications which form part of the prior art citable under Article 54(3) EPC1973 for novelty purposes only, under EPC2000 will be citable for all contracting states regardless of the designated States in the application and the intervening publication (in other words present Article 54(4) EPC1973 has been deleted).

vi) Second medical use:

And finally, Article 54 EPC2000 has been amended to state that purpose-limited product protection is available for second or further medical use of a known substance.

Whilst major substantive changes relating to how the EPO assess patentability, novelty and inventive step, for example, are not expected under EPC2000, it will be appreciated that with respect to procedural matters some of the changes will impact on practice before the EPO.

Further information can be found on patlaw-reform.european-patent-fice.org/epc2000/

By Karen Thirlwell

Several referrals have recently been made to the Enlarged Board of Appeal (the highest instance within the European Patent Office) concerning divisional applications. The first referral, made in T 39/03 and now pending under G 1/05, was made in August 2005. The second referral was made in decision T 1409/05 (March 2006) and is pending under G 1/06. In May 2006, a third referral followed, T 1040/04, pending under G 3/06. In the meantime, the three cases G 1/05, G 1/06 and G 3/06 have been consolidated. It is hoped that the outcome of the referrals will result in some clarification of the situation regarding divisional applications filed with the European Patent Office (EPO), which in recent years has become an area of increasing legal uncertainty.

Under Article 76(1) EPC, a European divisional application may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed. In so far as Article 76(1) EPC is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall have the benefit of any right to priority. A European divisional application, under Rule 25(1) EPC, may be filed up to but not including the date of the publication of the mention of grant of the parent application.

Offending subject-matter Current practice before the EPO, as set out in the current Guidelines for examination in the EPO, has been that, if an Examining Division is of the opinion that the divisional application includes subject-matter extending beyond the content of the parent application, the applicants will be given an opportunity to remove the offending subject-matter. Only if the applicants are unwilling to remedy the defect by removal of the offending subject-matter, will the divisional

application be refused under Article 97(1) EPC due to non-compliance with Article 76(1) EPC.

Enlarged Board of Appeal The first referral to the Enlarged Board of Appeal occurred because in recent decisions from the Technical Boards of Appeal views had been expressed which seemed to diverge from the current practice. The first referral to the Enlarged Board of Appeal was made in T 39/03. T 39/03 referred subsequently to other recent decisions from the Technical Boards of Appeal, including T 1158/01, T 720/02 and T 797/02, which suggested that a more limited practice with respect to divisional applications should be established. For example, whether a “nested claims” requirement, which applies in particular to divisional applications filed from earlier divisional applications, as set out in T 720/02 and T 797/02 had to be established.

As a result of the first referral to the Enlarged Board of Appeal, the EPO issued a practice notice in the Official Journal stating that until the Enlarged

nal applications



Nested claims required when branching-off a European divisional patent application?

as problematic, since there are no indications in the EPC that a different interpretation of the wording “content of an earlier application” should be used if the “earlier application” is a divisional application. The Board states that there is in particular no indication that in such a case the term “content” should be equated with the “the matter for which protection is sought” (as claimed on filing) – an interpretation which would be contrary to the established meaning of that term.

In T 1409/05 the following questions are referred to the Enlarged Board of Appeal:

1) In the case of a sequence of applications consisting of a root (originating) application followed by divisional applications, each divided from its predecessor, is it a necessary and sufficient condition for a divisional application of that sequence to comply with Article 76(1) EPC, second sentence, that anything disclosed in that divisional application be directly, unambiguously and separately derivable from what is disclosed in each of the preceding applications as filed?

2) If the above condition is not sufficient, does said sentence impose the additional requirement

- a) that the subject-matter of the claims of said divisional be nested within the subject-matter of the claims of its divisional predecessors?
- or
- b) that all the divisional predecessors of said divisional comply with Article 76(1) EPC?

Board of Appeal has issued its decision in the case G 1/05, all proceedings before EPO first-instance in which the decision depends entirely on the Enlarged Board’s decision will be suspended.

The third referral, T 1040/04, is quite similar to the referral made in T 39/03, but specifically addresses the question whether a granted patent may be amended during opposition proceedings, whereas the first referral only considered the amendment of patent applications. The third referral is pending under G 3/06.

In T 1409/05, the Board of Appeal seems to offer some hope with respect to re-establishing the status quo, questioning the additional requirements expressed in earlier decisions, such as T 720/02, etc. The second referral was made because the Board stated that its views were not “in line with the ratio decidendi of several recent decision of other boards of appeal”. Thus in T 1409/05 it was considered appropriate to refer questions to the Enlarged Board of Appeal in order to ensure uniform application of the law. In particular, the Board regards the above-mentioned “nested claim” requirement

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Question 1) asks the Board to address the issue of divisional applications of divisional applications. In particular, the Board asks whether the subject-matter of the divisional application must be derivable from what is disclosed in each of the preceding applications as originally filed.

Question 2a) explicitly asks the Enlarged Board of Appeal to state whether the “nested claim” requirement of T 720/02 and T 797/02 is correct. In other words, may the claims of the second divisional be drawn from any part of the earlier divisional application as filed? (Not just the claims as argued in T 720/02 and T 797/02.)

Question 2b) explicitly asks the Enlarged Board of Appeal to state whether the divisional of the divisional application is also invalid if it transpires that the first divisional has added subject-matter.

An answer of “no” to questions 2a) and 2b) would lead to a more liberal approach closer to the current practice. Answers of “yes” to questions 2a) and 2b) would reflect the more limited approach suggested in, for example, T 720/02 and T 797/02.

The three referrals have been consolidated and are pending under G 1/05, G 1/06 and G 3/06, and the Enlarged Board of Appeal will issue a single decision on the topic.

Whilst G 1/05 may be asking the Enlarged Board of Appeal to tighten up the present practice, the reasons in G 1/06 would appear to be suggesting

to the Enlarged Board of Appeal that the present practice is correct and requirements, such as the “nested claim” requirement have no legal basis in the EPC. However, until the outcome from the Enlarged Board of Appeal is known, there is a large degree of legal uncertainty with respect to how European divisional applications will be treated in the future. In the meantime, it is advisable to discuss the subject-matter of the divisional application



Until the outcome from the Enlarged Board of Appeal is known, there is a large degree of legal uncertainty with respect to how European divisional applications will be treated in the future.



to be filed prior to filing with the patent attorney concerned. In particular, extra care should be taken with respect to all aspects of possible added subject-matter. Extra care should also be taken with respect to filing divisional applications from divisional applications. Further, in cases where the parent application includes a plurality of inventions (for example, as a result of a well-founded non-unity objection), it may be advisable to ensure that all the remaining inventions for which any protection may be desired at a later date, are either included in the claims of one divisional application filed directly from the parent, or that the remaining inventions are covered in the claims of separate divisional applications filed from the parent application whilst the parent is still pending.

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