

**CA/PL 7/99**

Orig.: German

Munich, 2.3.1999

SUBJECT: Revision of the EPC: Articles 52(4) and 54(5)

DRAWN UP BY: President of the European Patent Office

ADDRESSEES: Committee on Patent Law (for opinion)

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#### SUMMARY

The deliberations on the removal of Art. 52(4) EPC are based on a proposal from the *epi* which was discussed and endorsed at a special session of SACEPO on 11 September 1998 (CA/PL 2/99; see also CA/16/98 Add. 1, the content of which is identical with that of SACEPO 2/98 Rev. 1). Patent practice in this regard was previously discussed at the 5th session of the European Round-Table on Patent Practice in May 1996.

It is in the public interest that efforts be made to promote the inventive development of the state of the art in the field of medical (ie surgical, therapeutic and diagnostic) methods. This could serve as an argument for not excluding this entire technical field from patent protection. Any abuse of patent protection can be combatted effectively by way of compulsory and statutory licences. Inventions in this field whose exploitation would be contrary to *ordre public* or morality are already excluded from patenting under Art. 53(a) EPC.

Consideration should therefore be given to removing Art. 52(4) EPC so that in future medical like all other methods are patentable in principle, provided the invention solves a technical problem. As a consequence, Art. 54(5) EPC should be removed as well and thus the extraneous special provision allowing the patenting of the first medical use of a known substance would be eliminated. Consideration would then have to be given to deciding how medical practitioners and veterinary surgeons can continue to be protected effectively from patent law restrictions when treating individual patients.

## **I. BASIS FOR THE EXCLUSION OF MEDICAL METHODS FROM PATENTING**

1. Under Art. 52(4), first sentence, EPC, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability on the grounds that they are not susceptible of industrial application. On the other hand, under the second sentence of that provision, products, substances and compositions for use in any of those methods are not excluded from patentability.
2. The exclusion of medical methods from patenting is based on the assumption that, for ethical and social reasons related to ensuring provision of medical services for the public, the exercise of medical skills should not be restricted or hindered by patents as a matter of principle. A doctor is not in "industry" (van Empel, "The Granting of European Patents", 1975, Chapter II, Section E2, points 117f, pages 63f). The Enlarged Board of Appeal has noted in this regard that the intention of this provision is to free from restraint non-commercial and non-industrial medical and veterinary activities (G 5/83, OJ EPO 1985, 64).
3. This exclusion was and is in line with the law in the contracting states of the EPC. Even before this provision was included in the EPC, medical methods already occupied a special position in the case law of the contracting states, despite not being specifically mentioned in their statute law. Nor does the Strasbourg Convention of 27 November 1963 on the Unification of certain Points of Substantive Law on Patents for Invention - on which Articles 52-57 EPC are largely based - contain any special rules for medical methods.
4. Later, under the WTO/TRIPs Agreement of 1994, the contracting states of the WTO were expressly granted the possibility of excluding from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Art. 27(3)(a) TRIPs). This provision, however, merely grants the contracting states the option of taking such action, and by no means imposes an obligation on them to do so.
5. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions (OJ EC L 213/13) expressly excludes from its scope of application provisions of national patent law on medical methods (recital 35).

6. As part of the deliberations on the revision of the EPC, it is necessary to examine whether it is still justifiable to exclude all medical methods from patentability, how legal practice has developed in this area on the basis of the decisions of the boards of appeal, and whether the real intention of the provision to exempt medical practitioners and veterinary surgeons from patent rights when treating individual patients directly should not be achieved in other more appropriate ways. In this regard it is necessary to examine whether it is justifiable to exclude entirely from patentability useful inventions for maintaining or restoring the health of humans and animals and thereby run the risk of failing to use or impeding the role of patent protection in promoting innovation in this technical field of public interest.

## II. GENERAL CONSIDERATIONS REGARDING THE PATENTING OF MEDICAL METHODS

7. The primary purpose of patent protection is to promote technical progress. To refuse patent protection for certain inventions designed to maintain or restore the health of humans or animals per se rules out the possibility of promoting - through patent protection - innovation and investment for research purposes in this very important technical field. In the field of medicine in particular, it is in the public interest that efforts be made to promote the inventive development of the state of the art. Social and ethical considerations might therefore argue in favour of allowing the patenting of medical methods too. Any abuse of patent protection could be effectively combatted through compulsory or statutory licences. Inventions whose exploitation would be contrary to *ordre public* or morality are already excluded from patentability under Art. 53(a) EPC.
8. If patent protection is available and a patent application is filed, the application must disclose every invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Art. 83 EPC). The exclusion clause contained in Art. 52(4) EPC therefore has a detrimental side effect in that it prevents further developments in this technical field - so important to the public health care system - from being made known to the general public, at least through patent applications. Moreover, those who cannot obtain patent protection for their invention will try, for as long as possible, to keep secret the technical teaching they have developed. It is therefore likely that the removal of Art. 52(4) EPC would achieve the desired effect that medical methods are disclosed in patent applications to a far greater extent than hitherto, thereby making them accessible to the general public.

### III. DECISIONS OF THE BOARDS OF APPEAL AND PATENT PRACTICE IN THE FIELD OF MEDICAL INVENTIONS

9. According to the decisions of the boards of appeal - which are largely in line with the decisions of the national courts of the contracting states on identical national provisions - inventions under Art. 52(4) EPC are excluded from patentability only if actually carried out **on the body** of live human beings or animals. **Diagnostic** methods applied on tissues or fluids after they have been removed from the human or animal body are not excluded from patentability in so far as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas the treatment of blood by dialysis with the blood being returned to the same body is excluded (Guidelines for Examination in the EPO, C-IV, 4.3).
10. Furthermore, according to the decisions of the boards of appeal, **diagnostic** methods used to obtain measurements from the body are not excluded from patentability if they merely provide interim results which in themselves do not allow a decision to be taken on any medical treatment necessary. Such methods include, for example, X-ray examinations, nuclear magnetic resonance tests, as well as measurements of blood pressure and other blood parameters (T 385/86, OJ EPO 1988, 308; T 400/87, unpublished). As far as **diagnostic** methods are concerned, Art. 52(4) EPC is therefore construed as an exclusion clause narrowly in practice, with the result that a diagnostic method practised on the human or animal body is excluded from patentability only if both the examination and the establishing of symptoms on the basis of the examination results are performed on a living human or animal body (see T 385/86, loc cit.).
11. Unlike other technical fields where claims with **technical and non-technical features** are permitted (such as inventions in the field of computer software), a claim directed to a method (or, where appropriate, the operation of a device for performing a method) is covered by Art. 52(4) EPC as soon as one of the steps in the method is classed as being diagnostic, surgical or therapeutic (consistent board of appeal case law, see eg T 82/93, OJ EPO 1996, 274, applying T 820/92, OJ EPO 1995, 113, and T 182/90, OJ EPO 1994, 641). "In considering whether a request for a particular set of claims is allowable under Article 52(4) EPC, the critical question is whether there is any disclosure of a method **none of whose steps fall under the prohibition of Article 52(4) EPC**, ie none of whose steps are either a method for the treatment of

the human or animal body by therapy or surgery, or a diagnostic method practised on the human or animal body" (T 82/93, loc. cit., No. 1.4). In this regard, it is irrelevant whether this step is explicitly mentioned in the claim or only implicitly comes to light when the method is carried out (T 182/90, loc cit., No. 2.5.1).

12. **Therapeutic** methods are designed first and foremost to cure specific symptoms and therefore by definition can only be carried out on the living body. The patentability of **a method for operating a therapeutic device**, such as an implanted device for controlled drug administration or a pacemaker, depends on whether or not a **functional link** and hence a **physical causality** exists between the method and the effect of the device on the human or animal body. Hence, a method for **monitoring the operation of an implanted therapeutic device** is patentable so long as there is no functional link between the claimed method and the effects of the device on the body, in other words so long as it does not - like a drug administration device - administer a dose of medication prescribed by a medical practitioner; in the case at issue, the method related to the measurement of drug flow in an insulin pump (T 245/87, OJ EPO 1989, 171).
13. On the other hand, a method **for operating a therapeutic device** is not patentable as a method **for therapeutic treatment** of the human (or animal) body if the method leads to the **termination of a clinical disorder**; in the case at issue, the method related to the operation of a pacemaker for arresting a tachycardia (T 426/89, OJ EPO 1992, 172). "If a patent as granted only contains claims which, **on their proper interpretation**, each define a method of operating a device which is in fact a 'method for treatment of the human or animal body by therapy or surgery', the patent cannot be maintained as granted having regard to Article 52(4) EPC" (T 82/93, loc. cit., Headnote III). Hence not every **technical method for operating a device** necessarily constitutes a "**technical method**" not covered by Article 52(4) EPC. It depends in each case on the "proper interpretation" of the claims as formulated.
14. It can therefore be noted that the definition of a diagnostic method contained in Art. 52(4) EPC is construed by the boards of appeal as an exclusion clause narrowly, whereas the general field of application of the article is widely construed and it is regularly applied even if only one step in a method is classed as being diagnostic, surgical or therapeutic in nature. This delimitation of the scope of Art. 52(4) EPC gives rise to casuistic and case-specific jurisprudence which makes it difficult to predict decisions and highlights the problems associated with all exclusion clauses.

#### IV. PATENT PROTECTION FOR PRODUCTS USED IN MEDICAL METHODS

15. Under Art. 52(4), second sentence, EPC, exclusion from patentability does not apply to **products for use in medical methods**, and in particular not to substances or compositions (medicinal products). Thus the therapeutic treatment of human beings or animals with medicinal products is excluded from patentability, but not the medicinal product itself.
16. Moreover, Art. 54(5) EPC further provides that substances or compositions, even when comprised in the state of the art, are to be regarded as showing novelty provided they are to be used for the first time for a medical method under Art. 52(4) EPC ("first medical use").
17. According to the decisions of the Enlarged Board of Appeal, a European patent may not be granted under Art. 52(4) EPC with claims directed to the **use** of a substance or composition for **the treatment of** the human or animal body **by therapy**. The Enlarged Board of Appeal has nevertheless admitted patent claims directed to the **use** of a substance or composition **for the manufacture of a medicament** for a specified new and inventive **therapeutic application** (G 5/83, loc cit.).
18. Art. 54(5) EPC and the decisions of the Enlarged Board of Appeal, which have made patent protection possible for further medical uses too, are only in fact justifiable to the extent that they are thought to possibly "compensate" for the exclusion from patentability of medical methods under Art. 52(4) EPC. The removal of Art. 52(4) EPC would also mean that it would no longer be justifiable to allow patent protection for the first medical use of a substance under the extraneous Art. 54(5) EPC which regards a substance comprised in the state of the art as being new.
19. If Art. 52(4) EPC were to be removed, the methods referred to therein would be patentable like every other method, so long as the invention solves a technical problem. If Art. 54(5) EPC were to be removed, substances and compositions would be subject to the absolute novelty requirement set out in paragraphs 1 to 4 of that provision, even if they are used for the first time for therapeutic purposes. In the case of a new therapeutic effect for a substance or product already known (first and further medical uses), however, patent protection would be available in the form of use claims.

## V. PROPOSAL ON PATENT PROTECTION FOR MEDICAL METHODS INCLUDING EXEMPTION OF MEDICAL PRACTITIONERS AND VETERINARY SURGEONS

20. A point to be considered if medical methods were made patentable in general is whether medical practitioners and veterinary surgeons should continue to be exempt from the effects of patent protection in their individual treatment of patients. One option would be an exemption clause similar to Art. 27 (c) CPC. According to Art. 27(c) CPC and corresponding provisions in the national patent laws of the contracting states, the rights conferred by a patent do not extend to "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". Such an exemption could stipulate that the right conferred by a patent does not extend to individual surgical or therapeutic treatment of the human or animal body by a medical practitioner or veterinary surgeon and individual diagnosis practised on the human or animal body. Medical practitioners and veterinary surgeons would thereby not be liable under patent law for actions taken in the course of using medical methods.
21. Such exemption of medical treatment from patent law restrictions would apply in particular to individual treatment by medical practitioners and veterinary surgeons acting as "natural persons". In the case of clinics using medical methods on a large scale "commercially", the justification for such an exemption is questionable. If clinics were not generally subject to patent protection for medical methods, the latter would in practice be worthless. In fact, the introduction of patent protection for medical methods would itself give clinics the possibility of compensation for being subject to such protection, since it can be assumed that they in particular would seek patent protection for such methods. They would thus have to respect patents for medical methods, but on the other hand they would be able to claim patent protection for any methods they themselves develop.
22. In this context, attention is drawn to the law of the United States, according to which medical methods are patentable without any restriction, although a similar form of exemption from liability when using such inventions has recently been enshrined in law (35 USC 287 c)(1)).
23. Another possible solution would be to restrict the rights conferred by a patent for medical methods in a general way by allowing the use of a patented medical method via statutory licences; use of the method would then not constitute a patent infringement but the patent proprietor would be accorded the right to reasonable compensation.

## VI. SUMMARY

24. If Art. 52(4) EPC were to be removed, the medical methods currently considered as not susceptible of industrial application would in future be patentable like all other methods, so long as the invention solves a technical problem.
  25. As a result, the justification of Art. 54(5) EPC, with its extraneous special provision for protection of the first medical use of known substances and compositions, would lapse. If Art. 54(5) EPC were to be removed, use patents could be granted for the first and each further medical use of a known substance in accordance with general principles.
  26. Just as patent protection does not extend to the extemporaneous preparation of patent protected medicines in pharmacies and related actions, the extemporaneous treatment of human beings or animals by medical practitioners and veterinary surgeons could continue to be exempt from patent law restrictions. An alternative option would be to consider restricting the rights conferred by patents for medical methods in a general way to claims for compensation.
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