

# METHOD OF TREATMENT INVENTIONS UNDER THE EPC: WHAT KIND OF PROTECTION CAN YOU GET?

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## 1. Introductory Comments

Unlike US patent law which does not exclude methods of treatment from patent protection, Article 52(4) of the European Patent Convention [EPC] contains the exclusion of methods for treatment by surgery or therapy and diagnostic methods from patent protection. Article 52(4) EPC, first sentence reads as follows:

*Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1.*

Article 52(4) EPC thereby provides one of the few exceptions to patentability as defined in Article 52(1) EPC which reads as follows:

*European patents shall be granted for any inventions which are susceptible of industrial application, which are new and involve an inventive step.*

It is noted that Article 52(4) EPC by way of legal fiction excludes method of treatment inventions from patent protection.

Thus, Article 52(4) EPC takes precedence over Article 57<sup>1</sup> which states that

*An invention shall be considered as susceptible of industrial application if it can be performed or used in any kind of industry including agriculture.*

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<sup>1</sup>Decision of the Technical Board of Appeal T 116/85; cf. O.J. EPO 1989, 13

The methods excluded by Article 52(4) EPC are the result of policy. The intention of said policy was according to the Enlarged Board of Appeal only to prevent non-commercial and non-industrial medical and veterinary activities from being restrained by patent rights.<sup>2</sup>

## 2. General Considerations

Article 52(4) EPC, first sentence, represents an exclusion clause and, hence, should be **narrowly** construed and should not apply to treatments of the human or animal body which are not therapeutic in character or do not constitute a surgical or diagnostic method. The following comments shall give guidance to the reader as to what should be considered if patent protection is desired for an invention involving the treatment of the human or animal body.

According to ample case law of the Boards of Appeal, a claim directed to a method must not contain a single therapeutic step (cf. also section 2.2 infra for the definition of "therapeutic") in order not to violate Article 52(4) EPC.<sup>3, 4</sup>

The criterion whether a measure was performed by a medical practitioner or another person having medical knowledge or under the supervision of such a person is **not** sufficient to decide whether the method step is objectionable under Article 52(4). The medical contents of the practitioner, however, would be a useful

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<sup>2</sup>Decision of the Enlarged Board of Appeal G 5/83; cf. O.J. EPO 1985, 64

<sup>3</sup>Decision of the Technical Board of Appeal T 820/92; cf. O.J. EPO 1995, 113

<sup>4</sup>Decision of the Technical Board of Appeal T 82/93; cf. O.J. 1996, 274

indication. In Decision T 385/86 the Board held that a method involving interaction with the human or animal body susceptible of industrial application is patentable if it can be used with a desired result by a technician without special medical knowledge and skills.<sup>5</sup> A further hint pointing to a method of treatment excluded from patentability by Article 52(4) EPC is if the method **has** to be performed by or under the supervision of a physician.<sup>6</sup>

## 2.1 Types of Treatment excluded by Article 52(4)

Article 52(4) mentions three types of treatments, i.e. surgery, therapy and diagnosis which are basically independent from each other and do not mutually restrict each other. According to case law, their exclusion from patentability requires that the treatments are performed on the living human or animal body. Method of treatments by surgery, therapy or diagnosis on dead human or animal bodies are thus not excluded from patentability.<sup>7</sup> In line with this, the treatment of body tissues or fluids outside of the human or animal body or methods of diagnosis practiced thereon are not excluded by Article 52(4) EPC unless the tissues or fluids are not recycled to the donor body.<sup>8, 9</sup>

## 2.2 Meaning of “Therapy“ as defined by European Case Law

In a first definition by an Appeal Board, the term “therapy“ was defined to be the treatment of a disease in general or the curative treatment in the narrow sense as

<sup>5</sup>Decision of the Technical Board of Appeal T 385/86; cf. O.J. EPO 1988; 308, in particular point 3.5.2 of the Reasons for Decision

<sup>6</sup>Decision of the Technical Board of Appeal T 24/91; cf. O.J. EPO 1995, 512

<sup>7</sup>Guidelines for Examination within the European Patent Office July 1999, C-IV, 4.3

<sup>8</sup>*Id.*<sup>7</sup>

<sup>9</sup>Decision of the Technical Board of Appeal T 144/83; cf. O.J. EPO 1986, 301

well as the alleviation of the symptoms of pain and suffering.<sup>10</sup>

In subsequent case law<sup>11, 12</sup>, it was decided that therapy also encompasses prophylactic treatment. Thus, therapeutic treatments can be summarized as being measures directed to the maintenance (prophylaxis) or restoration (therapy) of health.

Furthermore, the question was raised whether also the treatment of symptoms should be encompassed by the exclusion from patentability by Article 52(4) EPC. In Decision T 81/84<sup>13</sup> the question was decided for the treatment of menstrual discomfort. Although caused by natural circumstances, the Board held that said symptoms (menstrual discomfort) overlap with and are often indistinguishable from symptoms of a disease or injury. The Board concluded that it would be impossible and undesirable to distinguish between basic and symptomatic therapy, i.e. healing or cure and mere relief. Thus, the treatment of menstrual discomfort was considered to be a therapeutic treatment and therefore excluded from patentability according to Article 52(4) EPC. However, in a separate case - which will be discussed in the following - an Appeal Board came to a different conclusion.

There is an increasing interest noticeable for the use of pharmaceutical compositions comprising a therapeutically active ingredient for non-therapeutical purposes. Examples for non-therapeutical uses are, e.g. the use of the drug seldinafil (VIAGRA) for increasing the sexual vitality of healthy individuals or the use of choline or derivatives thereof for accelerating recovery from exhaustion after physical exercise. In this respect the question

<sup>10</sup>*Id.*<sup>9</sup>

<sup>11</sup>Decision of the Technical Board of Appeal T 19/86; cf. O.J. EPO 1989, 24

<sup>12</sup>Decision of the Technical Board of Appeal T 290/86; cf. O.J. EPO 1992, 414

<sup>13</sup>Decision of the Technical Board of Appeal T 81/84; O.J. EPO 1998, 207

arises whether the non-therapeutic effect obtainable after administration of the drug can be separated from the therapeutic effect of the drug or whether the patient populations receiving the drug for non-therapeutic purposes and therapeutic purposes differ from each other.

In a recent Decision of the Technical Board of Appeal the question had to be decided whether the use of choline or a derivative thereof for increasing the acetyl choline level in the brain and the tissue, thereby reducing the perception of fatigue in a person about to participate in major exercise or in a person having performed a major exercise would represent a therapeutic method in the meaning of Article 52(4) EPC and would therefore be excluded from patentability. The use of choline for the treatment of muscle diseases and hardness was disclosed in the prior art. The Board considered that in said case the two effects of choline are not inseparably linked or correlated, but on the contrary, are readily distinguishable because they involve groups of persons (or patients) undoubtedly distinct. The prior art group of persons consists of patients known to have a muscular disease, muscular injury or epilepsy, whereas the second group comprises healthy persons who will receive no therapeutic benefit from the treatment. Moreover, the times necessary for obtaining the different effects (days for the therapeutic effect and minutes or hours for the non-therapeutic effect) appeared to be so different that no unwanted overlap of the treatment could occur.<sup>14</sup> Furthermore the Board held that a condition of fatigue induced by the performance of exercises is a transitory physiological condition caused by natural circumstances and removable by simple rest. Pain or serious suffering do not appear to be manifestations of fatigue, which therefore is not comparable with the pathological state typical of a disease or an injury. Thus, the perception of fatigue is not comparable

<sup>14</sup>Decision of the Technical Board of Appeal T 469/94; not yet published in the O.J. EPO

with the relief of pain, discomfort and incapacity which has been considered in Decision T 81/84.<sup>15</sup>

Therefore, in light of Decision T 469/94<sup>16</sup> both method and use claims without the need for the formulation as second medical use claims should be patentable provided that (i) the effect is not a therapeutic effect or (ii) the therapeutic and non-therapeutic effect are clearly separable from each other.

### 2.3 Surgical Methods

According to the Guidelines for Examination in the European Patent Office (Guidelines), surgery defines the nature of the treatment rather than its purpose.<sup>17</sup> Thus, invasive methods which require the use of a scalpel are considered to be excluded by Article 52(4) EPC. Said reasoning in the Guidelines is further outlined by the reference to surgical methods as being, e.g. a method of treatment by surgery for cosmetic purposes or for embryo transfer as well as surgical treatment for therapeutic purposes. Interesting to note, surgical methods are excluded from patent protection regardless of whether they serve a therapeutic purpose or cosmetic purpose or any other purpose.

### 2.4 Diagnostic Methods

According to Article 52(4) EPC, diagnostic methods practiced on the human or animal body are excluded from patentability. It should be noted that diagnostic testing of samples which were taken from the living human or animal body, e.g. blood, sputum, or urine do not constitute diagnostic methods excluded from patent protection. In Decision T 385/86<sup>18</sup> the Board ruled that the only diagnostic methods to be excluded from patent protection were those performed on the living body and

<sup>15</sup>*Id.* 13

<sup>16</sup>*Id.* 14

<sup>17</sup>*Id.* 7

<sup>18</sup>*Id.* 5

providing results which immediately enabled a decision to be taken on a particular line of medical treatment. On the other hand, methods providing only interim results (e.g. measurement of blood pressure or blood sugar, x-ray or NMR examinations) were thus not diagnostic methods within the meaning of Article of 52(4), first sentence, even if they could be utilized in making a diagnosis.

In said Decision T 385/86 (*supra*) the Board outlined the essential elements of a diagnostic method within the meaning of Article 52(4) as comprising:

- Recording the case history, observing, palpating and auscultating various parts of the body and carrying out numerous medical and technical examinations and tests (the examination and data gathering phases);
- Comparing the test data with normal values, recording any significant deviation (symptom), and
- finally attributing the deviation to a particular clinical picture (deductive medical decision phase).<sup>19</sup>

The Board pointed out that if only one of said essential elements was lacking, no diagnostic method within the meaning of Article 52(4), first sentence, would have been at issue and consequently said method would not be excluded from patent protection.

## 2.5 Cosmetic Methods

Cosmetic methods are generally considered to relate to non-therapeutic indications. It was found in Decision T 144/83<sup>20</sup> that cosmetic methods meet

<sup>19</sup>Brockhaus Enzyklopädie, volume 4, 1968, page 684; The New Encyclopaedia Britannica, Macropaedia, 1977, volume 5, page 684; La Grande Encyclopédie Larousse, 1973, volume 7, page 3833

<sup>20</sup>*Id.* 10

the requirements of industrial applicability in accordance with Article 57 EPC. In the event that the cosmetic administration would, however, necessarily define a treatment of the human body by therapy, the cosmetic method would be excluded from patentability according to Article 52(4) EPC.<sup>21</sup> Provided that the therapeutic and non-therapeutic (e.g. cosmetic) effects are distinguishable, the applicant may obtain acceptance of a claim by introducing the feature “cosmetic” or “non-therapeutic” in the respective method claim.<sup>22, 23</sup>

## 2.6 Methods of Contraception

In Decision T 74/93<sup>24</sup> the Board had to decide whether a claim directed to the use of a contraceptive composition for applying to the cervix of a female mammal capable of conception is excluded from patentability by Article 52(4) EPC. The Board noted that methods of contraception are not excluded *per se* from patentability as stipulated in Article 52(4), first sentence, EPC, since pregnancy is not an illness and therefore its prevention is not a general therapy according to Article 52(4) EPC.

## 2.7 Methods of Testing

The Guidelines also deal with the patentability of methods of testing a compound in an animal and make clear that the utilization of (healthy) test animals for test purposes in industry, e.g. for testing industrial products, would be patentable provided that the test animals are not prophylactically treated or cured from a disease.<sup>25</sup>

<sup>21</sup>Decision of the Technical Board of Appeal T 290/86; cf. O.J. EPO 1992, 414.

<sup>22</sup>Decision of the Technical Board of Appeal T 36/83; cf. O.J. EPO 1986, 295

<sup>23</sup>Decision of Technical Board of Appeal T 774/89 (not published in the O.J. EPO)

<sup>24</sup>Decision of the Technical Board of Appeal T 74/93; cf. O.J. EPO 1995, 712

<sup>25</sup>Guidelines for Examination within the European Patent Office, C-IV, 4.4

## 2.8 *In Vitro* Methods

A further option to delimit method of treatment claims from methods of treatment as excluded by Article 52(4) EPC is to insert "*in vitro*" into the method claim provided (i) the specification provides sufficient support and (ii) said claims provide acceptable protection. According to the authors' experience, the drafting of *in vitro* claims is in particular useful for applications relating to manipulation of cells or tissues, which can be performed outside of the living body) e.g. a one step in a gene therapy protocol.

## 3. First and Second Medical Uses of known Compounds

### 3.1 First Medical Use

Article 52(4), second sentence, rules that the provision of Article 52(4) EPC, i.e. exclusion of method of treatments from patentability, shall not apply to products, in particular, substances or compositions for use in any of these methods. Regarding the patentability of known compounds for use in the medical field, Article 54(5) EPC further states:

*[T]he provisions of [Article 54] paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a any method referred to in Article 52, paragraph 4, provided that its use for any method referred to in the paragraph is not comprised in the state of the art (emphasis and [ ] added).*

In the Decision of the Enlarged Board of Appeal G 5/83<sup>26</sup> the Enlarged Board observed that the inventor of a "first medical indication" could obtain purpose-limited product protection for a known substance or composition, without having to restrict himself to a certain galenic formulation particularly adapted for a specified therapeutic purpose. The appro-

priate protection for him was therefore in its broadest form a purpose-limited product claim, the only purpose being the compound use as a medicament.

Regarding anticipation of the claim, however, the following should be noted.

Novelty would not only be destroyed by the fact that the same specific therapeutic effect was already known in the art, but suffered also from the disclosure of any other specific therapeutic medication using the compound in question.

A first medical use claim could read as follows:

Compound X as a therapeutic substance (or a medicament).

A particular first medical use claim is the so-called kit-of-parts claim which was considered to be allowable in Decision T 9/81.<sup>27</sup> The Board had to decide on whether a claim directed to pharmaceutical products containing a compound A and a compound B as a combined preparation for simultaneous, separate or sequential use in cytostatic therapy, wherein the first compound was a known cytostatic agent and the second compound was a known mucolytic agent, was patentable. According to the documentary prior art available, the two active ingredients had never been used together for a new joint effect and were unknown as a composition.

The Board ruled:

*Combined preparations the individual components of which represent known therapeutic agents may be protected in a formulation corresponding to Article 54(5) EPC even when claimed as a kit-of-parts, providing those components forming a functional unity (true combination) through a purpose directed application (headnote).*

<sup>26</sup>Decision of the Enlarged Board of Appeal G 5/83; cf. O.J. EPO 1985, 64

<sup>27</sup>Decision of the Technical Board of Appeal T 9/81; cf. O.J. EPO 1893,372

The Board explicitly stated:

*As a kit-of-parts, however, it is not necessarily a true combination in view of the physical separation of the individual components. Mere loose association of components does not in itself turn them into a functional unity in which a necessary and direct interaction between the components is a precondition for the purposive use. Although components in the claimed combination do not enter into such a direct interaction with each other the indication of purpose for the combined therapy may re-establish the unity of the product as a functional amalgamation of its two components, if it represents a genuine restriction to the specified application (point 6 of the Reasons).*

Therefore, a kit-of-parts claim should be considered when the core of the invention is a novel combination of two or more known compounds for a therapeutic purpose and the product will be marketed in kit form.

### 3.3 Second (or further) Medical Indication

A second (or further) medical use claim for a compound X is appropriate when said compound has already been used in therapy but for a different indication.

#### 3.3.1 Wording of Claims

In the pharmaceutical field, the “normal” type of use claim, such as “Use of compound X for treating disease Y” is prohibited by Article 52(4), because such a claim is interpreted as a method of treatment by therapy which is not admissible under Article 52(4).<sup>28</sup> However, the Enlarged Board of Appeal allowed claims of the type:

Use of substance X for the manufacture of a medicament for therapeutic application Y.

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<sup>28</sup>*Id.*2

It should be noted that in accordance with said Decision claims are considered to be allowable which are directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even where the process of manufacture of the medicament as such does not differ from known processes using the same active ingredient.

#### 3.3.2 Novelty of Second Medical Use Claims

The following section provides options for rendering a second medical use claim novel over prior art teachings.

a) In the landmark Decision G 5/83<sup>29</sup> the Enlarged Board considered claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application patentable, even in a case in which the process of manufacture as such did not differ from known processes using the same active ingredient. The novelty of the claim relied upon the new purpose (or medical indication). Therefore, of course, a newly found medical indication for a known medicament can form the basis for a second medical use claim.

b) In a further case, T 19/86<sup>30</sup>, it was decided that novelty of a second medical use claim could also be established by the group of animals to be treated, the medical indication being known from the prior art.

It was held in said Decision that a therapeutic application was incomplete if the subject to be treated was not identified; only a disclosure of both the disease and the subject to be treated represented a complete technical teaching. The principle that the identification of a novel group of patients to be treated could render the second medical

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<sup>29</sup>*Id.*2, point 23 of the Reasons

<sup>30</sup>Decision of Technical Board of Appeal; published in O.J. EPO 1989,24

use claim novel was later on confirmed in Decision T 893/90.<sup>31</sup>

Therein, the Board had to decide whether the second medical use of a medicament for the treatment of a disease in sero-negative pigs was novel over the known use of the same medicament for the treatment of the same disease in sero-positive pigs. Thus, the only difference between said therapeutic applications was that the populations being treated differed in their immunological behavior.

c) A further possibility to confer novelty on a second medical use claim is by incorporating the mode of administration into the claim. In Decision T 51/93 it was acknowledged by the Board that the mode of administration, i.e., subcutaneous administration versus known intramuscular administration, could render the second medical use claim novel<sup>32</sup>.

d) When a prior art document and a claimed invention are both concerned with a similar treatment of the human body for the same therapeutic purpose, the claimed invention represents a further (new) medical indication as compared to the prior document within the meaning of the Decision G 5/83<sup>33</sup> if it is based upon a different technical effect. The question underlying said Decision was to decide whether the use of compositions including lanthanum salts for improved removal of plaque from teeth, thereby inhibiting tooth decay was different from a prior art use of lanthanum salts in dental composition for the purpose of depressing the solubility of tooth enamel in organic acids developed in saliva, thus strengthening the enamel so as to inhibit tooth decay. Although the final therapeutic purpose is the same in both cases, the Board held the use according to the opposed patent for

removing plaque to be novel and inventive in view of the prior art.

e) Another possibility to confer novelty on a second medical use claim might be seen in the indication of either dosage and/or the treatment regimen in which the medicament is applied to a patient. In the Decision T 570/92<sup>34</sup> the Board *inter alia* allowed the following claim:

*Use of nifedipine crystals having a specific surface of 1 to 4 sqm/g for the preparation of solid pharmaceutical preparations for obtaining long-lasting blood levels for oral treatment of hypertension, to be administered once or twice daily.*

The Board noted that the wording used did not serve to indicate to a doctor the frequency of administration actually intended when treating an individual patient but merely to convey the teaching that the success of the treatment was ensured if a medicament was administered not more than twice a day. Although not explicitly stated one may draw the conclusion that the administration of the drug once or twice a day is a critical feature which can establish novelty.

In this respect, it should, however, be mentioned that a different Board came in decision T 469/94 to a different conclusion regarding novelty of a second medical use claim due to the indication of the treatment regimen. Although the Board did not directly decide on novelty of the second medical use claim in view of the prior art, the only novelty conferring element was a different treatment regimen in the claimed invention. The Board expressed its concerns in an *obiter dictum only*.<sup>35</sup>

<sup>31</sup>Decision of the Technical Board of Appeal T 893/90; not published in the O.J. EPO

<sup>32</sup>Decision of the Technical Board of Appeal T 51/93; not published in the O.J. EPO

<sup>33</sup>*Id.* 26

<sup>34</sup>Decision of Technical Board of Appeal T 570/92; not published in the O.J. EPO

<sup>35</sup>Decision of Technical Board of Appeal T 317/95; not published in the O.J. EPO

#### 4. Scope of Protection of Patent Claims in the Medical Field

Generally, the scope of protection of a European patent claim is governed by Article 69 EPC, first paragraph which reads as follows:

*The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.*

Any infringement of a European patent is dealt with by national law (Article 64(3) EPC).

In the following the main emphasis will be laid on the scope of protection in Germany.

In Germany the scope of protection of a patent is to be interpreted in the same way regardless of whether the patent represents the German part of a European patent or is a national German patent.

##### 4.1 Scope of Protection of First Medical Use Claim

The first medical use claim is considered to be a **purpose-limited** product claim wherein the purpose forms an essential element of the claimed teaching. The scope of protection will be limited to the indicated purpose. In the Decision of the German Federal Supreme Court "Antivirussmittel"<sup>36</sup> the Board had to decide on a case wherein the first medical use of a known compound has been discovered. The single patent claim reads as follows:

"Anti-virus agent, characterized in that it contains 1-amino adamantane or 1-amino adamantane hydrochloride."

The Federal Supreme Court considered the medical indication (anti-virus) to be a limitation of the product claim, although

<sup>36</sup>BGH "Antivirussmittel" GRUR 1987, 794

the composition had not previously been known as a medicinal product. An indication free claim wording, hence, would have been possible, which option, however, was not chosen by the applicant.

Thus, to generally obtain the broadest scope of protection for a first medical use claim, a too narrow indication of the purpose should be avoided. Therefore, preferably it should be indicated in the claim that the product is useful only as a medicament and additional, more narrow medical indications - such as antiviral - should be omitted.

##### 4.2 Scope of Protection of Process Claim

A claim directed to e.g. cosmetic methods or *ex vivo* diagnostic methods is considered to encompass the particular sequence of method steps which can also encompass the use of particular products. Contrary to processes of manufacturing, the aforementioned methods of treatment generally should not protect the object resulting from the treatment. It should be noted that preparatory acts are also not protected by process claims.<sup>37</sup> For more details, see below, "use claims."

##### 4.3 Scope of Protection of Second Medical Use Claims

Use claims which are considered as process claims provide protection for a specific use of a product. In the medicinal field the use claims are of particular importance in cases where a new medical indication of a known product or a new treatment regimen with a known product is found. In accordance with the Decision "Hydroxyridin"<sup>38</sup> the German Federal Supreme Court decided that the scope of protection of such use claims covers the packaging of the product with instructions for the claimed use. This means that by analyzing the information given in a

<sup>37</sup>BGH "Heliumspeisung"; cf. GRUR 1992, 305

<sup>38</sup>BGH "Hydroxyridin"; cf. GRUR 1983, 729



packaging sheet a patentee can quite easily find and prove patent infringement of the use patent. It should be noted that the doctrine of equivalence is also applicable to use claims. The scope of protection might thus be extended to other uses than the specific one mentioned in the claim.

## 5. Recent Developments and Outlook

### 5.1 Gene Therapy

According to definition, gene therapy is the correction of disease-causing genes by recombinant genetic engineering of body cells (somatic gene therapy) or of cells of the germ line (germ line gene therapy). Furthermore, gene therapy can be divided into *ex vivo* and *in vivo* gene therapy, wherein the former relates to removing of body cells from a patient, treatment of said cells with a gene vehicle (i.e. a recombinant vector) and subsequent recycling of the treated cells to the patient, whereas the latter implies direct administration of the recombinant gene vector by, e.g. intravenous or intravascular administration.

**5.1.1** US patent practice differs significantly from the European patent practice regarding the grant of patents directed to gene therapy methods. In 1995, the USPTO granted a patent encompassing very broad claims relating to *ex vivo* gene therapy wherein claim 1 as granted reads as follows:

*A process for providing a human with a therapeutic protein comprising:*

*introducing human cells into a human, said human cells having been treated in vitro to insert therein a DNA segment encoding a therapeutic protein, said human cells expressing in vivo in said human a therapeutically effective amount of said therapeutic protein*<sup>39</sup>

<sup>39</sup>US patent no. 5,399,346 (Anderson et al.) issued March 21, 1995

In January 1999 the USPTO granted a patent encompassing claims directed to a gene therapy method for manipulating germ line cells of non-human mammals.<sup>40</sup>

**5.1.2** Both method claims considered to be allowable by the USPTO would have been rejected by the EPO for violating Article 52(4) EPC.

In the following the possibility of obtaining claims relating to aspects of somatic *ex vivo* gene therapy will be considered. Article 52(4) EPC precludes the patentability of the complete gene therapy method comprising the withdrawal of cells, the genetic manipulation of the cells, the recycling of the manipulated cells to human or animal patient bodies.

Regarding the patentability of single steps of the *ex vivo* somatic gene therapy method mentioned above, a method claim comprising the step of manipulating the cells removed from a patient with a recombinant gene vector would not be excluded by Article 52(4). Of course, such a claim might lack novelty if the manipulation step of the cells has been performed already for e.g. a scientific purpose, non-related to a gene therapy approach. Said method claim would simultaneously also cover the immediate product of said process, i.e. the manipulated cells. Claims directed to the use of transfected cells for the preparation of a medicament for the treatment of the patient's disease would be admissible as well.

## 6. Summary

This Article has endeavored to set forth the basic principles and recent trends in the assessment of patentability of methods of treatment by the Appeal Boards by the Appeal Boards of the EPO.

There is a large number of further case law concerning the patentability of

<sup>40</sup>US patent no. 5,858,354 (Brinster) issued January 12, 1999

inventions in the medical field. The discussed cases reflect the author's personal opinions of highly relevant case law which should be taken into account when drafting a patent application in the medical field. As the discussion shows, although methods of treatment of the living animal and human body are excluded from patent protection there is a fairly large repertoire of options for getting useful patent protection in this important field.