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D E C I S I O N
of 29 October 2004

Case Number: T 1020/03 - 3.3.4
Application Number: 96915698.3
Publication Number: 0827408
IPC: A61K 38/30, A61K 38/55
Language of the proceedings: EN

Title of invention:
Method of administration of IGF-I

Applicant:
GENENTECH, INC.

Opponent:
-

Headword:
Method of administration of IGF-I/GENENTECH INC.

Relevant legal provisions:
EPC Art. 52(1), 52(4), 53, 54(4), 54(5), 56, 82, 83, 84, 97(1),
112, 113
TRIPS Section 5 Art. 1, 2, 3, 28, 30

Keyword:
"Article 52(4) EPC complied with (yes) - decisions T 0317/95,
T 0056/97, T 0584/97, T 0004/98 and T 0485/99 not followed as
conflicting with G 0005/83"
"Article 54(5) EPC applicable (yes) - decision T 0004/98 not
followed"

Decisions cited:

G 0001/83, G 0005/83, G 0006/83, G 0001/98, T 0019/86,
T 0290/86, T 0893/90, T 0051/93, T 0254/93, T 0892/94,
T 0958/94, T 0189/95, T 0317/95, T 0056/97, T 0584/97,
T 0004/98, T 0485/99, T 0486/01, T 0836/01,
Bristol-Myers Squibb Company v. Baker Norton Pharmaceuticals,
[1999] R.P.C. 253 and [2001] R.P.C. 1,
Bristol-Myers Squibb v. Yew Tree Pharmaceuticals [Netherlands]
(2000) ENPR 26
Hydropyridine (BGH GRUR 83, 729 and OJ EPO 1984, 25)
Merck & Co Inc's Patents [2003] F.S.R. 298

Headnote:

Any use to which Article 52(4) EPC first sentence applies in circumstances where the composition has already been suggested for some therapeutic use, allows a second medical use claim to the preparation of the composition for that second medical use, irrespective of in what detail that use was specified, subject to the use being novel and inventive. For the purposes of novelty also under Article 54(5) EPC this depends on whether use for therapy is novel, irrespective of the detail with which the therapy is stated in the claim.



Case Number: T 1020/03 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 29 October 2004

Appellant:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office posted 13 May 2003
refusing European application No. 96915698.3
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairwoman: U. Kinkeldey
Members: R. Gramaglia
S. Perryman

Summary of Facts and Submissions

- I. The appeal lies from the decision of the Examining Division issued on 13 May 2003, whereby European patent application No. 96 915 698.3, published as WO 96/37216, was refused pursuant to Article 97(1) EPC. Basis of the rejection were claims 1 to 24 of the main request filed on 3 November 1997 and those of the first to fifth auxiliary requests filed successively.
- II. The claims of the main request rejected by the Examining Division are identical to those of the main request presently before the Board. Claims 1 and 13 thereof read as follows:

"1. Use of insulin-like growth factor-I (IGF-I) in the preparation of a medicament for administering to a mammal so as to sustain its biological response in the treatment of a chronic disorder in the mammal wherein the administration pattern of the medicament comprises administering a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF-I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, then discontinuing said administration by means of a continual lack of treatment or a lack of treatment for consecutive days over a period of days equal to or less than the number of days during which the IGF-I was previously administered, then administering a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF-I that is continuous or at least once a day consecutively over a period of days that provides the maximum biological response in the mammal, then

discontinuing said administration by means of a continual lack of treatment or a lack of treatment or consecutive days over a period of days equal to or less than the number of days during which the IGF-I was just previously administered, and repeating this pattern of administration and discontinuance of administration for as long as necessary to achieve or maintain sustained biological response in the mammal."

"13. Use of insulin-like growth factor-I (IGF-I) in the preparation of a medicament for treating chronic renal failure in a mammal wherein the administration pattern of the medicament comprises administering a therapeutically effective amount of insulin-like growth factor-I (IGF-I) to the mammal to provide an exposure to IGF-I for from about three to twelve days, then discontinuing said administration for from about two to seven days, then administering a therapeutically effective amount of IGF-I to the mammal to provide an exposure to IGF-I for from about three to twelve days, then discontinuing said administration for from about two to seven days, and repeating this pattern of administration and discontinuance of administration for as long as necessary to achieve or maintain sustained renal function in the mammal, said time periods of discontinuing administration being for a period of time equal to or less than the time period during which the IGF-I was just previously administered."

Claims 2 to 12 and 14 to 24 related to specific embodiments of the use of claim 1 or 13.

III. The reason given by the Examining Division for refusing the main request was stated as follows:

"I) According to the Board of Appeal in T 317/95, paragraph 4.5, the determination of the best individual treatment schedule, in particular the prescribing and modification of drug regimens used for administering a particular medicament, so as to comply with the specific needs of a patient, appear to be part of the typical activities and duties of the doctor in attendance in exercising his professional skills in curing, preventing or alleviating the symptoms of suffering and illness. These were typical non-commercial and non industrial medical activities which Article 52(4) EPC intended to free from restraint. Similar comments are made in T 584/97, paragraph 2.6 and T 56/97 paragraph 2.5.

The Examining division note that the use of such phrases as "...achieve or maintain sustained biological response in a mammal" in the main request, claim 1 indicated that the treatment regimen is specifically tailored to the individual patient [sic], presumably by the attending medical staff.

For this reason the Examining division believe that claim 1 is unacceptable under Article 52(4) EPC, as the above cited Board of Appeal decisions imply.

II) Although in the above cited cases the Board did not base their decision on Article 52(4) EPC, the Examining division sees no reason to disregard the statement made on three separate occasions.

It is also clear that when making these statements the Board were fully aware of G 5/83 and many of the decisions mentioned by the Appellant.

*III) In the case of the "mode of administration" decision, the physician would decide how best to treat the patient and **then** select and administer the manufactured medicament. The claim is intended to cover the manufacture and distribution of the product up to the point where it becomes available to the medical staff. The actual administration is not within the scope of the claims.*

In the present case the therapeutic application of the claimed second medical use impinges on the physician's decision making and treatment process. Even if the claim gives some guidance which may not have previously been known or obvious, the physician in this case would still need to determine the "maximum biological response", and then decide how best to proceed. Further treatment decisions and steps also vary and depend on the number of days the drug was previously administered, requiring decisions and action from medical staff. These decisions and actions are covered by the claims.

In the present case is [sic] does not appear that there is a new "mode of administration"; dosage or disease to be treated. The novel and inventive features [sic] of the present application is the method of treating patients in a cyclic "on/off" manner.

*In contrast to the decisions mentioned by the Applicant, in this case, the physician would need to refer to the terms of the claims **after** treatment had commenced. This is regarded as being unacceptable under Articles [sic] 52(4) EPC. This is irrespective of whether any new patient group could be treated by the present application."*

The decision under appeal also refused amended first, second, third and fifth auxiliary requests for not complying with Article 123(2) EPC, and an amended fourth auxiliary request for containing claims not complying with Article 52(4) EPC, the same ground as for the refusal of the main request.

- IV. A communication was sent, expressing the Board's provisional opinion. Oral proceedings were held on 29 October 2004.
- V. Insofar as they are relevant to the present decision, the arguments by the appellant can be summarized as follows:
- The present application was based on the finding that instead of continuous treatment with IGF-I of patients with chronic diseases, such as chronic renal failure, which became ineffective over time, cycles of treatment ("intermittent" treatment) using IGF-I could bring about a prolonged effective benefit.

- The claims were drafted as second medical use claims in accordance with decision G 0005/83 (OJ EPO 1985, 64), wherein the feature which imparted novelty to the claims was a medical activity, which was specifically a non-patentable non-industrial and non-commercial activity. Both "first" and "second" medical indication claim formats provided patentability where the novel and inventive aspect of a claim lay in a feature which was inherently unpatentable per se.

- According to decisions G 0005/83 (supra) and T 0019/86 (OJ EPO 1989, 25), the meaning of the expression "therapeutic application" had to be broadly construed as meaning any treatment or therapy which fell within the exclusion of Article 52(4) EPC.

- There was no logic in allowing claims relating to therapeutic applications which were a new route of administration (see decision T 0051/93 of 8 June 1994) or a new group of subjects (see decision T 0019/86, supra) and then refusing a claim relating to a therapeutic application for a new pattern of administration which achieved significant benefits to the patients being treated.

- Rather, since the claims on file were drafted in the form approved in decision G 0005/83 (supra), any question regarding patentability of the present invention should be directed to whether the claimed IGF-I administration regimen constituted a novel and inventive use of the medicament. These questions had to be answered in the affirmative since none of the

prior art documents disclosed the IGF-I treatment for a period of days, followed by a break and repetition of the treatment, and moreover, this treatment regimen provided for long term therapy with reduced side effects, as was apparent from Examples I to III of the application, which also showed for comparative purposes that prior "continuous" uses of IGF-I had not been successful.

- This finding brought about a potential increase in the market for IGF-I. It was an important consequence of the present invention that the scope of industrial applicability and marketability of IGF-I was increased dramatically, because of the many different types of patients for which IGF-I treatment is made possible. Using conventional administration regimens many groups of patients with particular chronic diseases could not be treated by IGF-I because of the long-term subsidence of the beneficial effects obtained in the short term and/or the high incidence of side-effects.

- The claimed subject-matter did not impinge on the clinical freedom of the physician performing what was the novel feature of the claims. Any medical activity which fell under the exclusion of Article 52(4) EPC did so because that activity would interfere with the freedom of the physician to treat a patient. However, claim 1 itself was to the process of manufacture of a medicament, although it was the medical activity which provided novelty to a further medical use claim. This was what the Enlarged Board referred to as the "special approach to the derivation of novelty". It could not be an

objection to a further medical use claim that the use under Article 52(4) EPC was spelt out in the claim. Therefore, the claim did not cover the typical activities and duties of a doctor in exercising his professional skills and therefore did not cover a medical activity excluded from patentability within the terms of Article 52(4) EPC. This was true whether the medical activity used a known compound to treat a different disease, or a known compound to treat the same disease, but via a different route of administration.

- Decision T 0317/95 (supra) was not relevant, as the administration regimen dealt with in this decision was found to be obvious, unlike the administration regimen of present claim 1.

VI. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 24 of the main claim request submitted on 3 November 1997 or one of the first to sixth auxiliary requests filed with the Statement of Grounds of Appeal.

Reasons for the Decision

1. The appeal is admissible.

Enlarged Board of Appeal decisions G 0001/83, G 0005/83 and G 0006/83

2. The question of what can be patented where a substance or composition is to be used for the treatment of the

human or animal body, in a situation where the use of that composition is already known for some form of such treatment, was decided by the Enlarged Board of Appeal in seven parallel decisions of 5 December 1984, all with the same text, of which decisions G 0001/83 (Hoechst), G 0005/83 (Eisai) and G 0006/83 (Pharmuka) were published respectively in OJ EPO 1985, 60, 64, 67 in German, English and French. These decisions will be cited in the following solely by reference to decision G 0005/83 published in English, the language of the present proceedings, but the Board considers that its comments apply whatever language text is referred to. Also for the sake of brevity hereinafter "composition" will be used as an abbreviation of "substance or composition" except in direct quotations, as nothing turns on the difference, if any, between a substance and a composition.

3. It appears to this Board that the issue to be decided in this case depends critically on what was then decided by the Enlarged Board in relation to Articles 52(4) and 54(5) EPC, so this will first be discussed in detail. The order made by the Enlarged Board of Appeal in decision G 0005/83 reads:

- "1. A European Patent with claims directed to the use may not be granted for the use of a substance or composition for the treatment of the human or animal body by therapy.*

- 2. A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a*

specified new and inventive therapeutic application."

4. The reasoning of the Enlarged Board that led to these conclusions starts in points 11 to 16 of its decision reading as follows:

"11. The European Patent Convention, in general, allows both method claims and use claims but whether any activity is claimed as a method of carrying out the activity (setting out a sequence of steps) or as the use of a thing for a stated purpose (the sequence of steps being implied), is, in the opinion of the Enlarged Board, a matter of preference. For the European Patent Office there is no difference of substance. In the context of the present case, this means that any artificial distinction according to which, when the invention concerns the employment of a substance or composition for therapy, a method claim excludes and a use claim includes at least the preparation of a pharmaceutical product, with instructions for use in the treatment of illness (which has been called in German the "augenfällige Herrichtung"), cannot be accepted, because in both cases the active substance or composition for therapy must be in a state capable of exerting its therapeutic activity and this necessarily means that the active material has been formulated and made up into doses.

12. Whilst, therefore, there can be no objection to "use claims" in general, the obvious objection to a patent "with claims directed to the use" being

granted for "the use of a substance or composition for the treatment of the human or animal body by therapy" is that it seems to be in direct conflict with the provisions of Article 52(4) EPC, in accordance with which "methods for treatment of the human or animal body by therapy ... shall not be regarded as inventions which are susceptible of industrial application" within the meaning of Article 52(1) EPC.

13. *For the reasons already given, in the considered opinion of the Enlarged Board, a claim directed to the "use of a substance or composition for the treatment of the human or animal body by therapy" is in no way different in essential content from a claim directed to "a method of treatment of the human or animal body by therapy with the substance or composition". The difference between the two claims is one of form only and the second form of claim is plainly in conflict with Article 52(4) EPC. Since this is so, no patent can be granted including any such claims: Article 97(1) EPC.*

14. *Claims directed to substances or compositions for use in any methods for treatment of the human or animal body, on the other hand, are unquestionably directed to inventions which are susceptible of industrial application within the meaning of Article 52(1) EPC. This is not only expressly made clear in Article 52(4) EPC, last sentence, but also to be deduced from the definition of "susceptible of industrial application" in Article 57 EPC, namely, that the invention "can be made or used in any kind of industry, including*

agriculture". The last sentence of Article 52(4) EPC, indeed, appears to be a statement of the self-evident, made out of an abundance of caution.

15. *Furthermore, Article 54(5) EPC provides that the general rules of law relating to novelty (Article 54(1) to (4) EPC) shall not exclude the patentability of any substance or compositions, comprised in the state of the art for use in a method referred to in Article 52(4) EPC, provided that its use for any such method is not comprised in the state of the art. Thus the inventor of a "first medical indication" can obtain purpose-limited product protection for a known substance or composition, without having to restrict himself to the substance or composition when in a form technically adapted to a specified therapeutic purpose. The appropriate protection for him is, therefore, in its broadest form, a purpose-limited product claim. No problem arises over its susceptibility of industrial application, within the meaning of Article 57 EPC.*

16. *Claims directed to the use of a substance or composition for the preparation of a pharmaceutical product are equally clearly directed to inventions which are susceptible of industrial application, within the meaning of Article 57 EPC."*

5. The difference between the type of claim that the Enlarged Board considered as forbidden, and that which it considered allowable lies in the explicit subject matter of the claim. A claim to the "use of a

composition for the treatment of the human or animal body by therapy" (or to "a method of treatment of the human or animal body by therapy with the composition") is directed to subject matter which Article 52(4) EPC first sentence expressly states shall not be regarded as an invention susceptible of industrial application. However a claim directed to the use of a composition for the preparation of a pharmaceutical product is equally clearly directed to an invention which is susceptible of industrial application, within the meaning of Article 57 EPC, and thus, by reason of its subject matter, outside the scope of Article 52(4) EPC first sentence.

6. The Enlarged Board further considered that for the special case where the intended purpose of the preparation of the composition was for this composition then to be used for the treatment of the human or animal body by therapy, then Article 54(5) EPC allowed the preparation of the composition to be treated as notionally novel, even if the medicament resulting from the preparation was not in any way different from a known medicament (see points 20 and 21 of decision G 0005/83). This is contrary to the normal position in patent law where the fact that a composition is prepared for an intended novel use does not allow the preparation of the composition to be treated as novel, if the composition and its preparation are the same as for other, known uses. But in such other cases the novel intended use would itself be potentially patentable which is not the case for treatments by therapy. As Article 56 EPC on Inventive Step refers to what is state of the art for the purposes of Article 54 EPC, the notional novelty derivable under Article 54(5)

- EPC from the intended use of a composition in a treatment by therapy, also allows recognition of inventive step for the preparation of the composition to be derived from the intended therapy not being obvious.
7. In decision G 0005/83 the Enlarged Board of Appeal was concerned with a second (or further) medical use in situations where a first medical use was already known. Thus when the Enlarged Board stated in point 2 of its order that "*A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application*" this Board understands the use of the word "specified" (in the German text "bestimmt", in the French text "déterminée") to be merely by way of contrast to the unspecified therapy allowable in a claim for a first medical use, and not as imposing any special conditions that a further medical use had to fulfil. Rather any use to which Article 52(4) EPC first sentence applied (see point 1 of the order of the Enlarged Board) in circumstances where the composition had already been suggested for some therapeutic use, would allow a further medical use claim to the preparation of the composition for that further medical use, irrespective of in what detail that use was specified, subject to the use being novel and inventive.
8. For a use to be treated as new it must be confined to what is new, and not merely be directed to any use of a physiological/pharmacological effect or mechanism which underlay a previous therapeutic use but where the effect or mechanism had not been identified as such.

Examples of such cases are decisions T 0254/93-3.3.2 of 14 May 1997 (claim to the use of a retinoid in the preparation of a topically administrable medicament for use in the prevention of corticosteroid-induced skin atrophy considered merely to represent more information about the known use, i.e. the explanation of the mechanism of action underlying the previous use, without ending up in a new purpose reflecting said effect) and decisions T 0189/95-3.3.2 of 29 February 2000 (see point 2.4) and T 0486/01-3.3.4 (see point 12). The Board observes that the physiological/pharmacological effects referred to in these three decisions did not end up in truly new useful application arising from e.g. the opening of a new field of clinical application, the healing of a different pathology or clinical situation, the creation of a distinct group of subjects (either end-users or patients) or new means/measures for the practise of the new use. Stated otherwise, no increase in "industrial activity" over the known use was seen to occur.

Other requirements of the EPC to be examined

9. Of course a further medical use claim would require examination as to compliance with the other requirements of the European Patent Convention on patentability, such as Article 82 EPC on Unity of Invention, given that a first use was known, Article 83 EPC requiring the invention to be disclosed in a manner sufficiently clear and complete to be carried out, and Article 84 EPC requiring the claims to be clear and concise. That the Enlarged Board did not mention these articles is merely attributable to its being concerned with what was and what was not allowable in view of

Articles 52(4) and 54(5) EPC. It cannot be taken as meaning that the claim form approved in the case of such a further medical use does not also have to meet these other requirements of the EPC.

10. Article 84 EPC also requires claims to be supported by the description. A review of the discussions in the various drafts to be found in the preparatory material of the various meetings and conferences which ultimately led to the European Patent Convention 1973, suggests however that the requirement for support of the claims was viewed rather as a formal matter to ensure that the description and claims had the same extent. If the claims were originally broader it was considered that it would be permissible to amend the description to remove this discrepancy. It was not viewed as a substantive ground of objection to claims on the basis of inutility, namely that the claims were too broad compared to any useful purpose suggested for their subject matter in the description. This formal view of the requirement of support also explains why it was not made available as a ground of opposition, and this refusal has been confirmed by the Diplomatic Conference on the EPC 2000 revision. These remarks are made merely to indicate the Board's opinion that if first or second medical use claims are considered too broad compared to any use disclosed in the description, Article 84 EPC would not appear available to force an applicant to cut down the scope of the claims.

11. A further medical use claim in the approved format (or formulated in the equivalent form of a claim directed to a process for the manufacture of the medicament using the substance cf. decision T 0958/94-3.3.2, (OJ

EPO 1997, 241)) must be treated as complying with Article 52(4) EPC irrespective of the detail with which the therapy is specified. The contrary view would not be consistent with the reasoning of decision G 0005/83, particularly as stated in points 16 and 19. The decision of the Enlarged Board treats the uses that fall under Article 52(4) EPC in broad terms (see point 1 of its order). Every therapy which falls within these broad terms that is not the first known therapy involving the composition, allows a claim in the approved form of making a preparation for this further use which claim will thereby avoid conflict with Article 52(4) EPC. There is no hint to the contrary in the decision of the Enlarged Board, and certainly no discussion of what conditions other than novelty a further medical use would have to fulfil for this form of claim not to fall foul of Article 52(4) EPC and to be taken into account under Article 54(5) EPC. It is the nature of patent claims to state an invention in a way covering numerous possible variations. A therapeutic use mentioned in a patent claim may be stated with more or less detail, but it will never be as specific as the therapy prescribed by a particular physician for a particular patient at any one time. There is no guidance to be found in the EPC as to what detail is required for a therapy to be recognized for the purpose of a claim for the use of a composition for some further medical indication. As stated above in point 7, this Board cannot read the Enlarged Board decision G 0005/83 as making any distinction other than between a first and a further medical indication. The Enlarged Board's decision certainly contains no guidance as to the specificity with which the therapy for a further medical indication has to be formulated,

and its reasoning as to why a claim to the use of a composition for the manufacture of a medicament is allowable despite Article 52(4) EPC does not depend on any discrimination relating to the detail with which a therapy is stated.

Does a broad view of what are allowable claims to use of a substance lead to interference with physicians' freedom?

12. The Boards of Appeal have no jurisdiction to consider questions of patent infringement, but in view of the statement in the decision under appeal that the claim refused affects the physician in some way unacceptable under Article 52(4) EPC, the Board will indicate the reasons why it considers that a claim formulated in the way approved by the Enlarged Board of Appeal in decision G 0005/83 prima facie cannot be considered as producing any results contravening Article 52(4) EPC, whose intention was, as stated in point 22 of that decision, to free from restraint non-commercial and non-industrial medical and veterinary activities.

13. As all Contracting States of the EPC except for Monaco are also parties to TRIPS, questions of the rights conferred by a claim can conveniently be discussed by reference to the provisions of TRIPS, on the assumption that the national provisions of the Contracting States conform with these requirements, without needing to consider the situation in each individual Contracting State.

14. Relevant Articles under Section 5 Patents are:

- 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application (*). Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

- 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

- 3. Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

- ...

(*) For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be

synonymous with the terms "non-obvious" and "useful" respectively.

Article 28 - Rights Conferred

- 1. A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owners consent from the acts of: making, using, offering for sale, selling, or importing () for these purposes that product;*

- (b) where the subject matter of a patent is a process, to prevent third parties not having the owners consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

.....

- Article 30 - Exceptions to Rights Conferred

- Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

.....

15. While TRIPS does not explicitly allow any exceptions to infringement such as the provisions excluding acts done privately and for purposes which are not commercial, or acts done for experimental purposes relating to the subject-matter of the invention, which provisions are commonly found in national legislation, such provisions can be presumed to be allowed under Article 30 TRIPS.

16. Assuming that each EPC Contracting State does wish to exclude from patentability therapeutic methods for the treatment of humans or animals for reasons of public health, this is permissible under Article 3 TRIPS and is the purpose served by Article 52(4) EPC. All EPC Contracting States will then necessarily also have to have some provision, whether by reference to Article 52(4) EPC, an equivalent national law or some equivalent legal doctrine concerning what is capable of amounting to a patent infringement, to the effect that the normal rights (see Article 28 TRIPS above cited) of the owner of a patent are restricted, so that the patent owner cannot prevent third parties not having the owners consent from the act of using a patented composition or the product of a patented process for therapy purposes or inciting others to do so. Provided the Contracting States have such provisions, and this can fairly be assumed as it is necessary to protect physicians from being sued for patent infringement for merely prescribing a composition for a course of therapy, or a nurse administering such a composition, (a patient him- or herself using the composition for such a therapy would presumably already be protected under an exclusion relating to private use for non-commercial purposes), then neither in the case of use for a first medical indication or for any further

medical indications can the patent proprietor sue the physician, or nurse, but could sue persons in the business of supplying (whether by manufacturing, importing or marketing) such composition for the purpose of the new medical use.

17. The reasoning in the decision under appeal that there is some interference with the freedom of the physician to prescribe what he or she thinks fit which conflicts with Article 52(4) EPC, seems to miss the whole point of why the Enlarged Board of Appeal in G 0005/83 decided that there was no conflict with Article 52(4) EPC, namely because the patent proprietor would have a remedy only against the maker or dealer in the composition. If there is a well-established (unpatented or no longer patented) other therapeutic use for the composition, then the proprietor may find it difficult to find any target to sue for patent infringement, the competing manufacturers and sellers may quite genuinely be manufacturing respectively selling it solely for the existing non-infringing use, and a physician who prescribes it for the patented second medical indication, even if he or she should refer to the patent, would, on the assumptions made as to national laws on infringement, not be infringing. Any problem would be that of the proprietor of the patent for the second medical indication, and not for any physician, nurse or patient.

Decision under appeal

18. For the above reasons this Board considers that following decision G 0005/83, a claim such as independent Claims 1 and 13 here under consideration

which take the form of use of a composition for the preparation of a medicament for a specified therapeutic use, will thereby avoid being in conflict with Article 52(4) EPC, irrespective of the degree of detail with which the therapeutic use is stated. As Article 16 of the Rules of Procedure of the Boards of Appeal states "*...Should a Board consider it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier opinion or decision of the Enlarged Board of Appeal, the question shall be referred to the Enlarged Board of Appeal...*" this Board would not be free to uphold the decision under appeal which deviates from decision G 0005/83 of the Enlarged Board of Appeal without first making a referral.

19. In support of its refusal of the claims under consideration under Article 52(4) EPC, the decision under appeal does not itself discuss Enlarged Board of Appeal decision G 0005/83, despite the applicant (now appellant) relying on it, but refers to three Board of Appeal decisions, namely T 0317/95-3.3.2 of 26 February 1999, T 0056/97-3.3.2 of 30 August 2001 and T 0584/97-3.3.2 of 5 December 2001, even though the decision under appeal acknowledges that in these three cases the reasoning stated in relation to Article 52(4) EPC was not relied on for deciding the issues before those Boards. This Board has also noted two further decisions which express similar views on the application of Article 52(4) EPC, namely decisions T 0004/98-3.3.2 of 9 August 2001 (OJ EPO 2002, 139), (point 8.1 in particular) and T 0485/99-3.3.2 of 29 April 2004. This Board considers the views on Article 52(4) EPC expressed in these five decisions to have no proper basis in the EPC and to be in conflict with decision

G 0005/83 of the Enlarged Board of Appeal, and this Board is not prepared to follow the views in these decisions. While for the purposes of Article 15(1) of the Rules of Procedure of the Boards of Appeal reading... "*Should a Board consider it necessary to deviate from an interpretation or explanation of the Convention contained in an earlier decision of any Board the grounds for such deviation shall be given, unless such grounds are in accordance with an earlier opinion or decision of the Enlarged Board of Appeal. The President of the European Patent Office shall be informed of the Board's decision*"...it might not be strictly necessary to deal with these five decisions in view of the existence of Enlarged Board of Appeal decision G 0005/83, this Board nevertheless considers that it will assist uniform application of the law if it points out in detail what points in these five decisions it disagrees with.

Decision T 0317/95

20. In case T 0317/95, there was an appeal from a decision of the opposition division which had found that independent claim 1 to a pharmaceutical product, and independent claim 10 in the form of a second medical use were novel, and that claim 10 met the requirements of Article 52(4) EPC, but that both claims lacked inventive step. In the reasons for decision T 0317/95 it is stated:

"4.5. *In considering of whether the instruction in claim 10 concerning the particular course of the administration of the two known drugs (ie the prescribed regimen) for the treatment of*

gastrointestinal disorders may be regarded as relating to a further medical indication, sight should not be lost of the reasons for which the Enlarged Board of Appeal allowed claims for a second or further medical indication in analogy to the fiction of novelty for first medical indications laid down in Article 54(5) EPC. The Enlarged Board stated that it is the purpose of the exclusion of medical treatments from patentability according to Article 52(4) EPC to free from restraint non-commercial and non-industrial medical and veterinary activities. To prevent the exclusion in Article 52(4) EPC from going beyond its proper limits it seemed appropriate to take a special view of the concept of the state of the art for second and further medical indications. It was apparently the intention of the Enlarged Board of Appeal to allow claims directed to a further medical indication, in order to provide a certain compensation for the restriction on patent rights in the industrial and commercial field resulting from Article 52(4) EPC, first sentence (see G 5/83, especially reasons, point 22).

This suggests that, when it comes to the assessment of the possible limits of what could indeed be recognised to be a further medical indication (new therapeutic application) within the meaning of decision G 5/83, it appears appropriate to consider the question of whether the sole distinguishing feature, which was introduced in the claim directed to a further medical use for the purpose of delimiting the

claimed subject-matter from the prior art, relates to non-commercial and non-industrial medical activities.

The board has no reason to question the appellants' submission that the pharmaceutical industry, too, is engaged in optimizing the use of drugs and medicaments by investigating the optimum regimen for their administration to achieve the maximum possible therapeutic effect.

Notwithstanding this, determination of the best individual treatment schedule, in particular the prescribing and modification of drug regimens used for administering a particular medicament, so as to comply with the specific needs of a patient, appear to be in the first place part of the typical activities and duties of the doctor in attendance in exercising his professional skills of curing, preventing or alleviating the symptoms of suffering and illness. These are, however, typical non-commercial and non-industrial medical activities which Article 52(4) EPC intends to free from restraint.

In any case, before the priority date of the contested patent, the medical practitioner was in the present case aware of the possibility of treating gastrointestinal disorders using the particular combination of drugs defined in claim 10. He was similarly in a position to prescribe an effective regimen for treating each patient according to his individual needs (see citation (1/6), loc. cit.)

In view of the preceding it appears questionable to the board whether the feature in the last half-sentence of claim 10, which in fact relates to the prescribing of a specific drug regimen for a basically known medical treatment, more specifically, to the concurrent administration of both the bismuth-containing agent and the H₂-receptor blocking agent for the treatment of gastrointestinal disorders, could indeed be considered to represent a further medical indication from which novelty could be derived on the basis of the principles set out in decision G 5/83.

It appears questionable, too, whether this feature indeed reflects a medical activity in the industrial and commercial field not excluded from patentability within the terms of Article 52(4) EPC, as maintained by the appellants.

4.6. *Since the main request and similarly the auxiliary requests have in any case to be dismissed on the ground to be dealt with in point 5 (below), there is no need to give a decision on the respondents' objections to claim 10 on the ground of lack of novelty and non-patentability under the terms of Article 52(4) EPC...."*

21. The statement in the last sentence of the first paragraph of point 4.5 of decision T 0317/95 beginning *"It was apparently the intention of the Enlarged Board of Appeal to allow claims to a further medical indication..."* does not take into account the clear distinction made by the Enlarged Board of Appeal

between an unallowable claim to use of a substance for treating any medical indication, and the allowable claims in the form of use of a substance for the preparation of a medicament for a specified therapeutic use, that is the distinction based on the different subject matter to which these two types of claims are directed. In each case the feature supporting novelty and inventive step will be the new treatment, but only the preparation of the composition is covered by the allowable claim, not the use of the composition for therapy. Nor is there any recognition that the Enlarged Board of Appeal came to its conclusions on the basis of the wording of Articles 52(4) EPC last sentence and 54(5) EPC which explicitly affirmed the patentability of any substance or composition comprised in the state of the art for use in a method referred to in Article 52(4) EPC provided that its use for that method is not comprised in the state of the art. These two articles make no distinction between use for a first medical indication and use for a further medical indication. The reason that the claims for use of a substance for preparing a medicament for treating a further medical indication must be more limited than such a claim for a first medical indication is the *ex hypothesi* existence of such a first medical indication, and not some limitation laid down in Article 52(4) or 54(5) EPC.

22. When in the second paragraph of point 4.5 decision T 0317/95 refers to the assessment of possible limits of what could be recognized to be a further medical indication within the meaning of G 0005/83, and considers it appropriate to consider whether the sole distinguishing feature relates to non-commercial and

non-industrial medical activities, decision T 0317/95 is embarking on an enquiry which could have been avoided if the Enlarged Board decision were followed. The Enlarged Board said that if the therapeutic application was novel and inventive, then a patentee could obtain protection for the use of a composition for making a medicament for use in this therapy even though the only novel feature was the therapy which itself was a non-commercial and non-industrial medical activity.

23. The third paragraph of point 4.5 of decision T 0317/95 by emphasizing only that the typical activities of a doctor (physician) consist in the determination of the best individual treatment schedule, in particular the prescribing and modification of drug regimens for administering a particular medicament, simply ignores that it is equally part of the physician's role to choose the particular medicament. Patients would certainly be surprised to learn that this is not part of their physician's function, as who else would be competent to make this critical choice? Yet the manufacture of the medicament may be patented because its composition is absolutely new, because its therapeutic use for any purpose is new, or because the particular process of manufacture is new. But not even in these situations does the EPC (see point 1 of the Enlarged Board of Appeals order point 1) allow a claim to the method of therapy as such, so the physician is protected in his own field (as are nursing staff) whereas patent protection for manufacture is not considered to be interference in this forbidden area. It is not, certainly nowadays, part of the ordinary task of a physician to manufacture his own medicaments:

these are bought from suppliers. The Enlarged Board decision merely allows obtaining of a patent covering the manufacture of a medicament for a further medical use. Even if the proprietor of such a patent can enforce it against a competing manufacturer or dealer, by proving that it was manufactured for the purpose of being used in the further medical indication, the patent will still not allow the patentee to interfere in the excluded area of the medical treatment itself, anymore than in the case of a first medical indication.

24. The first paragraph of point 4.6 of decision T 0317/95 states clearly that the decision in that case was not based on the ground of non-patentability under Article 52(4) EPC dealt with above. Rather the decision was based on lack of inventive step, which is a legal ground in conformity with decision G 0005/83 with which this Board would have had no quarrel. Nevertheless since the non-reasons of decision T 0317/95 relating to Article 52(4) EPC have been relied on in the decision under appeal, and are cited at p. 92 of the book Case Law of the Boards of Appeal (4th edition 2001) in the interests of a uniform case law this aspect of the decision needed to be dealt with.

Decision T 0056/97

25. Decision T 0056/97 concerns a case where the opposition division had maintained the patent in amended form on the basis of a claim 1 in second medical use form. The passages in that decision, which this Board considers to be in conflict with Article 52(4) EPC and the view expressed in Enlarged Board of Appeal decision

G 0005/83, appear in points 2.4 to 2.6 of decision
T 0056/97 set out below:

"2.4. *The above considerations lead necessarily to the question whether or not claim 1 is compatible with Article 52(4) EPC. That article does not exclude medicaments and their preparation from being patentable, but has the purpose of ensuring that the actual use, by practitioners, of methods of medical treatment when treating patients should not be subject to restraint or restriction by patent monopolies. The Enlarged Board stated in decision G 5/83 (loc. cit., see especially Reasons, point 22) that the intention of Article 52(4) EPC is to free from restraint non-commercial and non-industrial medical and veterinary activities. Hence, in the present case the decisive question is whether claim 1 concerns a method of treatment as opposed to what is available for treatment.*

2.5. *To decide this question the board has to consider the features that effectively contribute to the core of the alleged invention as claimed. These features concern the administration of known medicaments, ie thiazide diuretics, in a particular prescribed dosage regimen or a particular unit dosage amount for the known treatment of hypertension without simultaneously inducing effective diuresis. They reflect in fact the discovery that a specifically chosen treatment regimen, which requires predetermination by doctors of the diuretic effective dosage range in relation to each particular thiazide diuretic used (see Example 1), provides the desired result. The*

specific amount of the thiazide diuretic to be administered is then conventionally selected by the doctor, as is the time and schedule of administration (see Example 1: the unit dose is administered in from 4 to 8 consecutive hourly doses, once or twice daily).

However, determination of the best individual treatment schedule, in particular the prescribing and modification of drug dosage regimens used for administering a particular medicament, so as to comply with the specific needs of a patient and to achieve the desired result of the treatment in an individual patient, calls first and foremost for the exercise by a medical practitioner of his professional skill in curing, preventing or alleviating the symptoms of suffering and illness. Such activities are typical of the non-commercial and non-industrial medical activities which Article 52(4) EPC intends should remain free from restraint. Against that background, the board has difficulty in seeing claim 1 as more than an unsuccessful attempt to obtain protection for a method of therapeutic treatment of the human or animal body by couching it in the form of a "Swiss type claim" (see also decision T 317/95 of 26 February 1999, not published in OJ EPO).

- 2.6. *Since the appellant/proprietor's main request must in any case fail for the reasons set out below, no final decision on the above issues is necessary in the present case."*

26. This Board already disagrees with how point 2.4 of decision T 0056/97 represents decision G 0005/83. Article 52(4) EPC first sentence stating that methods for treatment by therapy are not to be regarded as inventions is qualified by Article 52(4) EPC second sentence stating that this provision shall not apply to substances or compositions for use in such methods. It is this second sentence of Article 52(4) EPC which led the Enlarged Board to the conclusion that a claim directed to the use of a substance or composition for the manufacture of a medicament for use in a therapy was allowable under the provisions of Article 52(4) EPC as a whole, but in point 2.4 of decision T 0056/97 this aspect is not reflected. The sentence at the end of point 2.4 "*Hence, in the present case the decisive question is whether claim 1 concerns a method of treatment as opposed to what is available for treatment*" shows that in decision T 0056/97 the approach of decision G 0005/83 was not being adopted. The claim under consideration in decision T 0056/97 was in the form approved in decision G 0005/83, and thereby should be treated as potentially patentable as falling within the allowed area of the second sentence of Article 52(4) EPC and not under the prohibited area of the first sentence of Article 52(4) EPC. The decisive question to be answered in accordance with decision G 0005/83 was then whether the intended method of treatment for which the medicament was manufactured was novel and inventive, and not any further consideration under Article 52(4) EPC.

27. Point 2.5 of decision T 0056/97 further illustrates what this Board considers to be an incorrect approach to Article 52(4) EPC, by seeking to focus on the vague

notion of *"the features that effectively contribute to the core of the alleged invention"*, instead of focusing on whether the subject matter of the claim as formulated is allowable under Article 52(4) EPC. The considerations regarding Article 52(4) EPC made in decision T 0056/97 were superfluous, as appears from its point 2.6 which states that no final decision was made on this issue, the case being finally decided on the basis of lack of novelty or non-compliance with Article 123(2) EPC of the various requests. But the statement, even if superfluous to the decision in which it was made, needs to be criticized since it has given rise to difficulties in later cases, such as the decision under appeal.

Decision T 0584/97

28. In the decision under appeal, decision T 0584/97, point 2.6 was relied on by the Examining Division as supporting its views. This decision was considering a claim reading:

"1. Use of nicotine for the manufacture of a kit containing separate units of nicotine of varying concentration, such that at least one unit contains a sub-therapeutic dose of nicotine and at least one unit contains a therapeutic dose of nicotine for the treatment of a condition susceptible to nicotine therapy involving the separate or sequential administration of increasing doses of nicotine."

29. In addition to point 2.6 of decision T 0584/97, points 2.3 and 2.4 are also sufficiently relevant to Article 52(4) EPC to quote here, but point 2.5 dealing with kit of parts claims is too remote to require discussion. Points 2.3, 2.4 and 2.6 of decision T 0594/97 read:

"2.3. It must therefore be decided whether claim 1 of the patent in suit contains features which could be regarded as novel vis-à-vis the disclosure in document (1).

In that respect, as emphasised by the appellant, the Board notes that this claim is a "Swiss-type" claim drafted in the form approved by the Enlarged Board of Appeal in G 5/83 (OJ EPO, 1985, 64) to comply with the requirements of Article 52(4) EPC.

Accordingly, in order to compare claim 1 with the disclosure in document (1), it is necessary to construe claim 1 in the light of this decision.

The correct construction of this use claim is the following:

"Use of a substance (nicotine) for the manufacture of a medicament (a kit containing sub-therapeutic and therapeutic units) for therapeutic application (the treatment involving conditions susceptible to nicotine therapy involving the separate or sequential administration of increasing doses of nicotine)".

In fact and in essence, this claim amounts merely to the use of nicotine for treating conditions

susceptible to nicotine therapy, independently of its wording which is dictated by the Enlarged Board of Appeal's decision G 5/83.

In other words, what is here factually claimed is the use of nicotine for the manufacture of a medicament, without any further specified medical indication. Provided nicotine had never been disclosed before in relation with therapy, such a subject-matter could have been claimed under Article 54(5) as a medicament (First medical indication). This was however here not possible in view of the disclosure in document (1), and it is not the form of the claim chosen by the appellant.

Indeed, the appellant has worded its claim in the form suggested by the Enlarged Board of Appeal when more particularly considering the so-called second medical indication (see G 5/83, point 9, OJ EPO 1985, 65), i.e. cases in which the medicament resulting from the claimed use is not in any way different from a known medicament.

In its decision, provided the medicament is for a specified new and inventive application, the Enlarged Board of Appeal admitted that "the required novelty for the medicament which forms the subject-matter of the [second medical use] claim is derived from the new pharmaceutical use" (G 5/83, points 21 to 23).

In the present case, no such new pharmaceutical use over document (1) can be seen.

Even if account was taken of the description or the dependant claims of the patent in suit where specific diseases are mentioned (e.g. Alzheimer disease in claim 6; ulcerative colitis in claim 7), it can be seen that these indications are already disclosed in document (1). Furthermore, although arguing in this direction during the oral proceedings, the appellant did not make any attempt to amend claim 1 accordingly.

- 2.4. *In addition, according to the case law formed by subsequent decisions of the boards of appeal the concept of second medical indication has been extended to cover particular situations, among other cases, the treatment of the same disease with the same compound could also represent a novel therapeutic application when it is carried out on a new group of subjects which is distinguished from the former group (e.g. T 19/86, OJ EPO 1989, 24).*

During the proceedings, the appellant insisted on the absence of side effects achieved by the therapy according to claim 1 of the contested patent, the Board notes that this effect is mainly achieved when the patients to be treated are substantially non-smoking patients for whom the problem linked with the toxicity associated with administering nicotine arises. Claim 1 is, however, not restricted to such a group of subjects. Accordingly, this aspect cannot be taken into consideration for assessing the novelty of claim 1.

.....

2.6. *It is also true that document (1) does not disclose the specific regimen of the patent in suit involving the administration of increasing doses of nicotine from sub-therapeutic to therapeutic levels.*

As already mentioned above, the aim of the regimen is inter alia the achievement of tolerance in order to alleviate the toxicity associated with administering nicotine to non-smoking patients. Contrary to the unsupported submissions of the appellant during the oral proceedings, it cannot be accepted that this effect is achieved for the whole spectrum of patients, in particular the heavy smokers.

It also appears questionable whether this feature does indeed reflect a medical activity in the industrial and commercial field not excluded from patentability within the terms of Article 52(4) EPC.

This feature of the claim, which relates merely to the prescription of a specific drug regimen for basically known medical treatments, can not however be considered to represent a further medical indication from which novelty could be derived on the basis of the principles set out in decision G 5/83 (see 2.2).

In view of the above, the Board concludes that the subject-matter of claim 1 does not fulfil the requirements of novelty under Article 54 EPC.

Accordingly, there is no need to consider either the subject-matter of the other claims or the other grounds of opposition."

30. Whereas decision T 0584/97 explicitly concludes that the subject-matter of claim 1 does not fulfil the requirements of novelty, it does not emerge clearly whether this is because the treatment with increasing doses of nicotine is considered not to be novel, or is to be disregarded as a feature of the claim for not further explained reasons under Article 52(4) EPC or possibly Article 54(5) EPC. If the latter is the case, this Board considers that decision T 0584/97 is in conflict with decision G 0005/83, which would require the novelty of the therapy itself to be considered. Further this Board considers the approach of point 2.3 of reinterpreting the claim (see the statement: "...*In fact and in essence, this claim amounts merely to the use of nicotine for treating conditions susceptible to nicotine therapy...*") and thereby ignoring the claim's actual wording and subject matter as being an approach having no basis in the EPC, as in particular Articles 84 and 113(2) EPC require that the claim and its subject matter be considered in the text submitted by the applicant or proprietor.

Decision T 0004/98

31. In the case leading to decision T 0004/98 (OJ EPO 2002, 139) the Opposition Division had maintained the patent on the basis of an amended claim 1 reading:

"Use of a liposome composition effective to extend to at least 24 hours, the period of effective activity of a therapeutic compound which can be administered intravenously in a therapeutically effective amount and which is cleared in free form in the blood stream with a half-life of less than about 4 hours, comprising liposomes (I) composed of vesicle-forming lipids and between 1-20 mole percent of a vesicle-forming lipid derivatised with a polyethyleneglycol, and (ii) having a selected mean particle diameter in the size range between about 0.1 to 0.4 μm (microns), and the compound in liposome-entrapped form, for the preparation of a composition for intravenous administration at a dose of the composition which contains an amount of the liposome-entrapped compound which is at least three times such therapeutically effective amount."

32. In decision T 0004/98 it was held that the claim 1 could not be treated as novel as a second medical use claim (see point 8.1 quoted below) but could still be treated as a novel process claim for manufacturing a liposome composition (points 8.2 to 10.3 of decision T 0004/98). Only points 8.1 and 8.2 of that decision are relevant to the present case, and so will be quoted here:

"8.1. As generally understood, the concept of "therapy" or "therapeutic application" includes treatment of a particular illness or disease with a specified chemical substance or composition in a specified human or animal subject in need of such treatment. By comparison, the "three (or ten) times dosage"

feature fails to provide any indication of at least (i) the illness or disease to be treated or the ailment to be cured, (ii) the nature of the therapeutic compound used for treating or curing the disease and (iii) the subject to be treated. In the absence of the identification of any of these parameters (i) to (iii), the "three times (or ten times) dosage" feature actually relates to the intravenous (or subcutaneous) administration of an unspecified therapeutic compound in liposome-entrapped form in an amount, which is at least three (or ten) times the therapeutically effective amount of said unspecified therapeutic compound, for the treatment of an unspecified illness or disease in an unidentified patient or other human or animal subject. This being the case, the board fails to see how this feature could be construed as specifying a particular method of treatment or a therapeutic application within the meaning of Article 52(4) EPC. In accordance with the principles set out in decision G 5/83 (see especially Reasons, end of point 21) and the substantial body of case law which has been developed by the boards of appeal in this respect (see eg "Case Law of the Boards of Appeal of the European Patent Office", 3rd edition, 1998, I. C. 6.2, pp 98-103), the concept of "second (further) medical use" can only be applied to claims to the use of substances or compositions (here the liposome compositions defined in the claims) for the preparation of a medicament intended for use in a method referred to in Article 52(4) EPC. For the reasons given above, this is clearly not the case here.

- 8.2. *In view of the foregoing observations, the subject-matter of the above-mentioned independent claims is accordingly to be understood as relating to a non-therapeutic technical activity (process). The "three times (or ten times) dosage" feature can then only be construed as one of the process features characterising the claimed process."*
33. In the first sentence of point 8.1, decision T 0004/98 states that therapy includes something meeting three criteria, and these criteria are defined in more detail in the second sentence. Decision T 0004/98 then appears by the fourth sentence of point 8.1 to be saying that something not meeting these three criteria is excluded from being treated as a therapeutic application within the meaning of Article 52(4) EPC. These three criteria mentioned have no basis in any wording to be found in the EPC, and as an exclusionary definition of "therapy" seem quite arbitrary. To this Board it is not clear whether all three criteria have to be met simultaneously, or whether meeting one of these criteria is sufficient (the differently worded headnote suggests the latter).
34. This Board considers any attempt to define therapy by reference to particular detailed criteria an exercise in futility, as not being required by the EPC and not being something on which general assent is achievable in the absence of any guidance in the EPC, and so this Board will not itself attempt a definition. Decision G 0005/83 of the Enlarged Board of Appeal can be followed without requiring any detailed definition of therapy. As stated above in point 7 of this decision

the use of "specified new and inventive therapeutic application" in point 1 of the order in Decision G 0005/83 was merely by way of contrast to the unspecified therapy allowable in the case of first therapeutic indication. To distinguish over such first medical indication, the further medical indication must be specified in the claim with some degree of specificity. Any restriction on the breadth of claim allowable would however fall to be considered primarily under the provisions of Article 82 EPC on Unity of Invention, as for the further medical indication there must be some general inventive concept other than therapy as such, as the concept of therapy as such will have already been disclosed by the suggested use for a first medical indication. If the subject matter of the claim, as will be the case for a claim in the approved "Swiss" form, avoids the prohibited method of treatment by therapy of Article 52(4) EPC first sentence, then compliance with this provision does not need to be considered further, and certainly not for imposing restrictions on the breadth of the claim.

35. If the legislator had wished to allow patenting of the manufacture of a composition for use in a further method of therapy, but had wished the claims of any one patent to be restricted to meet specific criteria of specificity, then the appropriate legal provision of the EPC to modify would have been Article 82 EPC on Unity of Invention. This Board considers that only precise definitions by the legislator could ensure the universal assent needed to make the question of how specific the claims had to be to be patentable suitable for decision by an instance of the European Patent Office.

36. On the view taken by this Board there is a seamless fit, either a method of using a composition is not a treatment by therapy and therefore falls outside the provision of Article 52(4) EPC first sentence, and so is patentable subject to compliance with the other provisions of the EPC, or else a method is a treatment by therapy and therefore inside the provision of Article 52(4) EPC first sentence, and so not itself patentable, but use of a composition for making a medicament for use in such treatment by therapy is patentable for unspecified therapy as a first medical indication or for a specified therapy as a further medical indication, again subject to compliance with the other provisions of the EPC, in particular novelty and inventive step.
37. On the view taken in decision T 0004/98 point 8.1 the question even arises whether if a method of quasi therapeutic treatment was not specified with the detail there required, so that it did not qualify as a method of therapy, whether it could then be claimed as such, as being a method falling outside the provision of Article 52(4) EPC first sentence? A possible analogy could be seen for this in Enlarged Board Decision G 0001/98 (OJ EPO 2000, 111) relating to claims comprising but not identifying plant varieties. This Board considers such a result inappropriate, as it sees no analogy between the exclusion of Article 53(b) EPC to prevent overlap with a different regime of protection for plant varieties, and the provision of Article 52(4) EPC preventing the grant of patents on methods of therapy, and a further reason for not

adopting the views expressed in point 8.1 of decision T 0004/98 on the meaning attributable to therapy.

Decision T 0485/99

38. This decision concerns a use of a specified composition in the manufacture of an immunostimulatory pre-operative diet for post-operative stimulation of the immune system of patients subject to surgery. The Examining Division had refused the claim for lack of inventive step in relation to one document, whereas the Board of Appeal deciding the case remitted it for consideration of the novelty of a slightly modified claim over another document that had already been considered in the examination proceedings. The passage that this Board wishes to comment on reads as follows:

"3.6. From the point of view of the wording of claim 1 it has to be said that the only feature remaining with respect to document (1) is the fact that the intake of the diet is pre-operative.

Therefore, it remains to be investigated whether the pre-operative therapy as defined in the claim, which also deals with post-operative immunostimulation, can be distinguished from the therapy disclosed in document (1) by a different medical (physiological) effect due to this pre-operative administration and thus whether it relates to a functional feature leading to the therapeutic indication in the sense of G 5/83 or not.

If it does not, the use defined in such a way might restrict the medical practitioner's freedom when treating his patients (see T 56/97, unpublished in the Official Journal, points 2-2.5). Pre- or post-operative administration of the diet would then constitute methods for treatment of the human body and could thus not be regarded as patentable inventions under Article 52(4) EPC."

39. This Board disagrees with the statement of law appearing in this cited point 3.6, insofar as it approves and reflects the view of the law set out in decision T 0056/97 points 2.4 and 2.5, which for the reasons set out in points 26 and 27 above of this decision this Board does not agree with. This seems to have led in decision T 0485/99 to a remittal on the issue of novelty, whereas this Board would have viewed the issue to be treated as a question of inventive step, given that the pre-operative immunostimulation was accepted as not disclosed.
40. This Board sees nothing in the five decisions discussed that persuades it to alter its view of the law as summarized in points 7 and 11 above, and based on decision G 0005/83 of the Enlarged Board of Appeal.

Other considerations

41. Even if this Board did not already consider that the wording of Articles 52(4) and 54(5) EPC, and the decision of G 0005/83 required such broad allowability of claims in second medical use form, but that a choice was left open between a broad interpretation of these EPC provisions and a more narrow interpretation, this

- Board would consider it appropriate to choose a broad interpretation which does not require any restriction of the area where novelty can be looked for.
42. New and valuable fields of clinical application may relate to a newly identified distinct group of subjects (either end-users or patients) or new means/measures for the practise of the new use, as for example in decision T 0051/93 of 8 June 1994 (new physical means/measures for the subcutaneous use and new end-user (self administration)); or new groups of patients as in decisions T 0019/86 (OJ EPO 1989, 24), T 0893/90 of 22 July 1993, T 0290/86 (OJ EPO 1992, 414) and T 0836/01 of 7 October 2003. The realization of a new mechanism of action for a known composition may enable a further group of subjects to be treated using a known composition. In such a situation the claim of course may need careful wording for it to be restricted to the subjects for whom the therapy is novel.
43. The Board can see no reason why the person who develops a novel therapy by looking for the most effective way in which a known composition can be administered should a priori be said to lack merit to such an extent that even the limited form of patent protection of the second medical use form can be denied without an examination of whether the therapy is indeed novel and inventive.
44. As stated by the text book author Bertschinger (Bertschinger/Münch/Geiser in the Handbuch für die Anwaltspraxis, Band VI Schweizerisches und Europäisches Patentrecht, published 2002 by Helbing & Lichtinger, Basel, page 119, § 4.73, translation by the Board) "*The*

practical utility of the possibility to protect a "second indication" is not confined to cases in which an application has been found for an already established and proven medically active ingredient. This possibility is of at least equal utility in the not uncommon cases where a substance has attributed to it in the literature - sometimes only in passing - therapeutic properties without the substance ever having thereby been made available as a medicament; if someone now notes additional undescribed therapeutic properties of the substance, on the basis of which properties a valuable medicine can be developed, then the so found "first really useful indication" (the true indication), in terms of patent law is still a "second indication"; such an invention could not be patented at all except for the discussed way of protection."

45. This argument can be further extended to the case where a first described, or even experimentally tested, use has shown that the substance has such adverse side effects, or has rapidly diminishing biological response with use (tachyphylaxis), that the known treatment is not suitable for practical purposes. Someone who then comes up with a regimen of administration which avoids these disadvantages may in fact be the first to provide a really useful therapy, and should be able to enjoy the protection available for a composition for use in making a medicament to be used in this new treatment.
46. To provide a basis in the case law for allowing examiners to reject an application with a claim in Swiss form on some vague ground that despite this it impinges on the freedom of physicians contrary to Article 52(4) EPC, without any need to investigate

whether the therapy is indeed novel and inventive, cannot do justice to the needs of applicants, or in any way benefit patients. Physicians in ordinary practice are not likely to be put off from using new methods of therapy by fear of patent infringement, but rather by fear of being sued for medical malpractice by their patients if something should go wrong, or even losing their licence to practice. It is the very responsible task of physicians to treat their patients according to the best method known to the physician, and the more well-established the method is the more certain the physician can be of its success. However the knowledge as to the best treatments has to be gained somehow, from in vitro tests, in vivo tests on cells and animals, and clinical trials under specially supervised conditions. This needs to be financed. Allowing second medical use patents serves to increase the possibilities of someone undertaking the necessary research. If the possibility of obtaining a financial return is excluded less research is likely to take place.

Referral of a question to the Enlarged Board of Appeal

47. Article 112 EPC states:

(1) In order to ensure uniform application of the law, or if an important point of law arises:

(a) the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for

the above purposes. If the Board of Appeal rejects the request, it shall give the reasons in its final decision;

(b) the President of the European Patent Office may refer a point of law to the Enlarged Board of Appeal where two Boards of Appeal have given different decisions on that question.

48. The question of what therapies can give rise to an allowable claim in second medical use form is an important question of law simply by the number of cases in which it arises. However it appears to this Board that the answer thereto can be given based on decision G 0005/83 of the Enlarged Board of Appeal (and the simultaneously decided six other cases), namely that any novel and inventive therapy potentially allows a known composition to be claimed for use in the manufacture of a medicament for use in such therapy, either for use in (unspecified) therapy in general if the composition has never before been suggested in connection with a therapy, or for use in a specified further therapy, with "specified" merely indicating that it is restricted in some way to make it novel and inventive over the known therapy using such composition.
49. The Diplomatic Conference in November 2000 on the revision of the European Patent Convention explicitly approved of decision G 0005/83 and agreed amendments to the convention expressly intended to give an amplified legal basis for the legal conclusions arrived at in G 0005/83. Thus the exclusion of methods of treatment and diagnostic methods currently referred to in Article 52(4) EPC has been added as paragraph 53(c) EPC to the

two exceptions to patentability which appear in present Article 53(a) and (b) EPC, to make clear that they are excluded from patentability on the grounds of public health and not on the basis of a fiction of their lack of industrial applicability (see conference document CA/100/00 page 41). In addition Article 54 EPC is to be revised to have two subsections reading:

"54(4) The provisions of paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided its use for any method referred to in that paragraph is not comprised in the state of the art.

54(5) Notwithstanding paragraphs 2 and 3, the provisions of this article shall not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in any method referred to in Article 53(c), provided that such use is not comprised in the state of the art."

50. The reasons for the new Article 54(5) EPC are to be found in Explanatory notes to be found in the proposal of this provision by the Swiss delegation reading (MR/18/00 e):

*"The new **Article 54(5) EPC** eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further medical use of a substance or composition already*

*known as a medicine. This protection is equivalent, as far as the further uses are concerned, to that offered by the "Swiss type claim". In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a **specific** use. This limitation is intended to match as closely as possible the scope of protection provided by a "Swiss type claim"."*

51. This Board considers the word "specific" in proposed Article 54(5) EPC (respectively "spezifisch" and "spécifique" in the equivalent German and French texts) to be used only to point out the contrast to the unspecific use allowable in a claim to a first medical use, and not as requiring that any detailed criteria be met before a use for a therapy can be considered specific. Thus there only has to be some limitation that distinguishes over use for therapy in general. Taking any other view would leave the unanswerable question of with what detail a use in a method of therapy would need to be described to be considered as "specific" in the context of the proposed Article 54(5) EPC. The arguments given above in points 7 and 31 to 34 in relation to the use of "specified" in the order of Enlarged Board of Appeal decision G 0005/83 appear to this Board to apply equally to prevent any more limited interpretation of "specific" in proposed Article 54(5) EPC. The Board thus also sees no significance in the use of the words "specific", "spezifisch" and "spécifique" in the proposed Article 54(5) EPC compared to the slightly different terms, namely "specified", "bestimmt" and "déterminée", used in the order of the

Enlarged Board of Appeal in G 0005/83 to describe the allowable further therapeutic use.

52. On the view of the law taken by this Board the legal situation remains the same under the proposed amendments to the European Patent Convention as under the existing version. As the amended version is likely to come into force in some two or three years time, this seems a strong reason not to refer any question of law to the Enlarged Board of Appeal on the existing wording of the EPC. Further, such referral might itself cause doubt to arise, and cause work on pending cases to be suspended while the answer of the Enlarged Board of Appeal is awaited on a text of the law which will soon change.

Reference for the sake of uniformity of application of the law

53. Another reason for making a reference to the Enlarged Board of Appeal would concern uniform application of the law given the views expressed in decisions T 0317/95, T 0056/97-3.3.2, T 0584/97, T 0004/98 and T 0485/99 on what is excluded by Article 52(4) EPC and how novelty of further medical uses is to be treated under Article 54(5) EPC as presently formulated. The views set out in these decisions seem to this Board unarguable if the view of decision G 0005/83 on the existing Article 52(4) EPC is followed, and even less arguable on its proposed replacement by new Article 53(c) EPC.
54. The statement in decision T 0004/98 point 8.1 concerning therapy necessarily requiring details, might have an impact on what therapy can be considered to

provide novelty for the purposes of existing Article 54(5) EPC, and also be relevant under the new proposed Article 54(5) EPC, particularly in view of its reference to specific use. For the reasons explained above in points 7, 31 to 34, and 48, this Board does not consider the restrictive view such as in decision T 0004/98 appropriate. Neither this Board, nor the only party to this appeal, has any sympathy for such a restrictive view or sees any merit in it. If any question is to be referred to the Enlarged Board of Appeal on this, it should be in a case where a party, or a Board or the President under Article 112(1)(b) EPC, sees some merit in the view and supports it by cogent arguments.

55. This Board has also considered what is said in the Guidelines for Examination in the European Patent Office (December 2003) in particular Part C, Chapter IV, concerning second medical use type claims, but sees nothing there with which it would disagree. None of the above five cases containing views on the law affecting Articles 52(4) and 54(5) EPC with which this Board disagrees, are referred to in the Guidelines. If those concerned with laying down the Guidelines thus wish to ensure uniformity of application of the law, they could amplify the Guidelines if they agree with this decision, or make a reference of a question of law under Article 112(1)(b) EPC if they prefer a view of the law expressed in a decision which conflicts with the view taken in this decision.

Decisions of national courts

56. The Board is aware of the so-called "Taxol" cases in the Netherlands and the UK, relating to infringement of European Patent 584 001 having a claim 1 reading:

"Use of taxol and sufficient medications to prevent severe anaphylactic reactions for manufacturing a medicamentation for simultaneous, separate or sequential application for the administration of from 135 mg/m² up to 175 mg/m² taxol over a period of about three hours or less as a means for treating cancer and simultaneously reducing neutropenia."

57. To enable a comparison of the approaches to validity, it should first be noted that the same patent was also considered in the EPO, oral proceedings before an Opposition Division taking place at a date subsequent to the national decisions, to which decisions attention had been drawn. The Opposition Division, by a decision with written reasons published 16 May 2002, revoked the patent for lack novelty in view of the prior publication of the preliminary results of clinical trials sponsored by the patentee himself, of which no evidence had been before the Examining Division which had granted the patent, but which evidence had been relied on in the national proceedings. The Opposition Division in the interests of overall procedural efficiency and effectiveness also considered it appropriate to take position on inventive step by way of obiter dictum, and indicated that the claimed solution was obvious even if the feature of reduction of neutropenia were to have been recognized as a novel

- technical feature. The Opposition Division however considered that the claim did comply with the requirements of Article 52(4) EPC. The patentee did not appeal. On the facts as stated, the Board, in its present composition, considers that it would have come to the same conclusions and taken the same view of the law as was done by the Opposition Division.
58. In the UK, the English High Court in *Bristol-Myers Squibb Company v. Baker Norton Pharmaceuticals* ([1999] R.P.C. 253) found that the claim lacked novelty and inventive step. The learned judge, Jacob J. (as he then was), did not accept that the claim amounted merely to a method of treatment, but considered it to be directed to the manufacture of the medicines to be used in that treatment, and thus not to fall foul of Article 52(4) EPC or its UK equivalent (see paragraphs 50 and 51 of his decision). The EPO Opposition Division came to the same result.
59. On appeal the English Court of Appeal ([2001] R.P.C. 1), while agreeing with the learned judge below that the claim lacked novelty and inventive step, disagreed with him on Article 52(4) EPC, as the three learned appellate judges considered that the claim was directed to a method of treatment of the human body (see paragraphs 54-63, 90-94, and 107-112) and thus contravened Section 4 of the UK Patents Act 1977, the UK equivalent of Article 52(4) EPC. Further on novelty, they arrived at the view that "...*The novelty cannot lie in the method of use, but in the new therapeutic purpose for which the substance is used...*". On that basis the patent was found not to claim an invention that was new in the terms of Article 54 EPC on the

Court of Appeal's view of decision G 0005/83 (Eisai). (See paragraphs 87 and 88 at 2001 R.P.C page 27). The Court of Appeal also emphasized that the new use should be unconnected with the previously known use(s), and gave as an example of a new use to fight another illness or for prevention instead of cure (see paragraphs 85 and 86). While the result arrived at on novelty was the same as in the High Court and the EPO Opposition Division, the view of what in law was capable of creating novelty was different.

60. In the Netherlands "Taxol" case, the Court of Appeal in the Hague (see *Bristol-Myers Squibb v. Yew Tree Pharmaceuticals [Netherlands]* (2000) ENPR 26) refused relief on the grounds that there was a real possibility of at least partial nullification and revocation of the patent for insufficiency and lack of novelty. The Hague District Court (see point 5 of the Hague Court of Appeal judgement) had refused relief on the different ground that there was a serious, non-negligible possibility that the patent would be revoked as pertaining to a process for the medical treatment of the human body, making its grant hard to reconcile with Article 52(4) EPC in connection with Article 52(1) EPC. The Hague Court of Appeal did not base its decision on this ground of there being a serious possibility of violation of Article 52(4) EPC.

61. This Board is not aware of any later cases in the Netherlands on Article 54(2) EPC. It cannot be said with certainty whether or not there is a prevailing view in the Netherlands that a Swiss form claim can violate the provisions of Article 52(4) EPC.

62. Regarding Germany, it should be recalled that decision G 0005/83 (Eisai), did not only approve the Swiss form of claim, but also disapproved of granting claims in the form "Use of a substance or composition for the treatment of the human or animal body by therapy" (see Order point 1, and also point 17 of that decision for discussion of the German practice, and in particular of the decision of The Federal Court of Justice *Hydropyridine* (BGH GRUR **83**, 729 and OJ EPO 1984, 25). In doing so it did not follow German practice which allowed (and still allows) a claim in such form. With slight oversimplification, German practice can be described as allowing such a claim, leaving it to the court deciding on infringement not to enforce the claim against acts which exclusively take place in a non-commercial area, but to enforce it against manufacture and supply which can be identified as being for the claimed use.

Discussion of national decisions

63. The views of the law of the English Court of Appeal on Article 52(4) EPC and on novelty not being able to lie in the method of use, and on their view of the law expressed in decision G 0005/83 differ from the view of the law taken by this Board in this decision, and thus need discussion as to whether this difference makes a reference of a question of law to the Enlarged Board of Appeal appropriate, taking into account also the position in other Contracting States.

64. Since decision G 0005/83, the prevailing view taken by the Boards of Appeal has been that Swiss forms claims, by being directed at manufacture, avoid any conflict

with the provisions of Article 52(4) EPC. Certainly immediately after decision G 0005/83, the seven appeals in which the referrals had been made, were dealt with on the basis that claims in Swiss form by their very subject matter avoided conflict with Article 52(4) EPC. This view was also followed subsequently with the possible exception of the cases discussed above in this decision.

65. In considering the UK Court of Appeal Decision above referred to, the Board has also looked at the UK equivalent to Article 52(4) EPC, namely Section 4 of the UK Patents Act 1977 of which the relevant parts read:

"4(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

4(3) Subsection (2) above shall not prevent a product consisting of a substance or composition being treated as capable of industrial application merely because it is invented for use in any such method.

66. While Section 130 of the UK Patents Act 1977 on interpretation contains in subsection (7) a declaration that the provisions of inter alia Article 4 of the Act *"..are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention..."* it must be noted that the corresponding

provision of Article 52(4) EPC has substantially different wording, and the Board would comment that its interpretation of Article 52(4) EPC and of decision G 0005/83, would have appeared to it much more problematic if Article 52(4) EPC had been worded, in all official languages, to correspond exactly to the wording of Section 4(2) and (3) of the UK Patents Act 1977. However the wording of this UK legislation is not something that the Boards of Appeal can take account of in interpreting the European Patent Convention.

67. In the UK, the House of Lords has yet to express its views on Articles 52(4) and 54(5) EPC. The UK Court of Appeal decision was followed only with reluctance by Jacob. J. (as he then was) in *Merck & Co Inc's Patents* [2003] F.S.R. 298, the reluctance being expressed in paragraph 80 in the following words:

"I conclude that the claim is in substance to a method of treatment of the human body by therapy. I do so with regret. For patents are provided to encourage research. If new and non-obvious improved methods of administration of known drugs for known diseases are not patentable in principle - even with a Swiss form claim, then there will be less of a research incentive to find such methods. Giving the exception a very narrow scope, so that any preparation used in such a method is protectable only by the artificial construct of a Swiss form claim, would be a research incentive. But I must follow the current state of interpretation of the exception in Bristol-Meyers."

68. In the absence of a uniform practice of the courts of the Contracting States regarding the interpretation of Article 52(4) EPC, this Board cannot see that any change away from the view that claims in Swiss form comply with this provision, as enunciated in decision G 0005/85, would ensure greater legal uniformity in Europe, while it would depart from the established case law of the Boards of Appeal. The Board thus sees no useful purpose that could be achieved by referring any question of law on Article 52(4) EPC to the Enlarged Board of Appeal under the provisions of Article 112 EPC.
69. For an understanding of the Board's views on novelty and Article 52(4) EPC as stated in this decision, it may also be useful to state the fundamental considerations moving the Board, namely that any invention in the pharmaceutical field is in essence a new method of using a composition in a therapeutic treatment, and that any ingenious chemistry is merely incidental to this. Use of any composition at a low enough level is likely to have negligible effect for good or ill, whereas use at too high a level may lead to severe ill effects, or possibly a fatality. Any invention lies in finding a use (including both level of dose and the form of application) where at least some types of patient will receive a net benefit from application of the composition. There is no guarantee that any such beneficial use exists.
70. A pharmaceutical research team will include as an integral and essential part a physician, whose task it will be to determine when enough knowledge is available to obtain permission to begin the first clinical trials, and to supervise such clinical trials and collate the

information obtained to establish the limits within which a composition can generally be expected to be safe and effective for use. Clinical physicians during such trials have the particularly delicate task of obtaining information while acting in the best interests of their patients, even to the extent of breaking off the trial. Once a product has received marketing authorization for particular uses, any physician will normally wish to prescribe it (if at all) at what he judges the appropriate dose and form of application for his patient within the limits of what the manufacturer has indicated as safe.

71. The fact that the marketing of pharmaceuticals is tightly controlled within the Contracting States by the relevant control authorities, including for the EU the European Medicines Agency, means that for most pharmaceuticals it can be established for what therapeutic treatment(s) they are marketed. This makes it practicable to grant patent rights with Swiss form claims which are enforceable against identifiable suppliers of an old substance for a specific new therapeutic use, but not against the persons ultimately responsible for this use, the physicians. The Board does not see Swiss form claims, even when they refer to steps to be taken by a physician, as interfering with the liberty of the physician to do the best for the patient, but only as restricting the purpose for which suppliers may act freely. If the freedom of the physician to treat his patient in the best manner possible requires him to be free to obtain a composition from any source, the granting of patents even for novel compositions would be difficult to

- reconcile with such extensively interpreted freedom for the physician.
72. Against the background of these considerations, the Board interprets decision G 0005/83 as allowing Swiss form claims directed to the use of a composition for manufacture of a medicament for a specified new and inventive therapeutic application, where the novelty of the application might lie only in the dose to be used or the manner of application. This Board allowed such a claim, where only the manner of application was new, already eleven years ago in T 0051/93 of 8 June 1994. The discussion in decision G 0005/83 concerning further medical indications did indeed refer to use for treating a new illness. But the Board regards this significant only of the fact that most further medical use claims will refer to a new illness, as in that case novelty and inventive step are more likely to exist than in the case of a minor modification of the treatment known for an existing illness. The logic of decision G 0005/83 allowing claims to further medical uses of known compositions, seems equally applicable to any use of such known composition for a new and inventive treatment which cannot be claimed as such because of Article 54(4) EPC first sentence.
73. A certain logical discomfort caused by decision G 0005/83 treating as the basis for novelty under Article 54(5) EPC, the very feature which Article 52(4) EPC first sentence said shall not be regarded as inventions which are susceptible of industrial application, was assuaged in decision G 0005/83, by treating this as a pure fiction to ensure the freedom of physicians (but not the freedom of suppliers), and

hopefully will be removed for all Contracting States when the revisions of the EPC come into force.

74. Despite not agreeing with this narrow focus view on novelty, the Board has nevertheless considered what the practical effect would be of adopting the view that novelty cannot lie in the method of use, but only in the therapeutic purpose for which the substance is used. For a time, until Applicants adopted countermeasures such as including in the claim some vague feature at least arguably making the composition new, it would probably simplify examination and rejection of applications in this field, as the examiner would merely have to establish that lack of novelty existed by looking at the composition and the illness(es) to be treated, ignoring any other features of the method set out in the claim. However it is not always easy to tell whether a claim does relate to treating a new illness compared to the prior art, and in such cases it would remove the possibility of establishing novelty over mere "paper" publications by inserting an indication of the range of possible doses, or a new form of administration. Given that quite a short document can suggest billions of compositions for treating hundreds of illnesses, how to distinguish over prior art with such a narrow focus approach to novelty would become much more problematic than at present.

75. A change to this narrow focus view on novelty would not be in the interests of those doing research in pharmaceuticals. It would probably slow the increase of knowledge on how medicines can most effectively be used. It might cause a reduction of prices, but not even this would be certain if there was simply a shift of

promotion and research expenditure to products for which patent protection was obtainable.

76. Further, such an approach to novelty would involve an artificial form of claim construction. If the legislator wants this narrow focus approach, this Board would prefer to see this implemented by an explicit change to this effect in the European Patent Convention. In the European Patent Office no doctrine of binding precedent applies, this decision, for example, being binding only on the Examining Division to which the case is being remitted. For a Board of Appeal to take the retrograde step of adopting the narrow focus approach to novelty, it would need to be persuaded of its need, and have very persuasive arguments for doing so if it hoped to be followed by others. Neither is the case for this Board.

77. Given that amendments to the EPC will enter into force in some years time rewording the provisions of Article 54 EPC on novelty, this Board rather than referring to the Enlarged Board of Appeal any question of law on whether this narrow focus approach should be applied on the existing wording of the EPC, would prefer to wait and see if a European consensus on this question emerges and whether the legislator wishes to take any action.

Conclusions

78. The Board thus considers that a reference in this case of any question of law to the Enlarged Board of Appeal is not appropriate, but is giving its reasoning at length to assist clarification of the situation.

79. In view of the foregoing the board concludes that claims 1 and 13 of the main request are directed to potentially patentable subject matter avoiding the prohibition of Article 52(4) EPC first sentence, and remits the case for further consideration of novelty and inventive step, depending on whether the intended method of therapy is itself novel and inventive, taking into account all the features of the use in the claim, as well as for consideration of the other requirements of the EPC mentioned in point 9 above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of the main claim request filed on 3 November 1997.

Registrar:

Chair:

U. Bultmann

U. M. Kinkeldey