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D E C I S I O N
of 11 May 2005

Case Number: T 0866/01 - 3.3.02

Application Number: 92902903.1

Publication Number: 0516811

IPC: A61K 31/47

Language of the proceedings: EN

Title of invention:
Euthanasia compositions

Patentee:
Michigan State University

Opponents:
Knötgen, Anita, Dr. et al.
Hüppe, Hubert, MdB
Intervet International bv, Patent Department

Headword:
Euthanasia Compositions/MICHIGAN STATE UNIV.

Relevant legal provisions:
EPC Art. 52(1), 52(4), 53(a), 53(b), 54(1), (2), (5), 56, 57, 58,
69, 84, 99, 100(a), 102(3), 106, 107, 108, 115, 128(4),
123(2), (3), 133(4), 134(2), (4)
EPC R. 26(2)(c), 27(1)(a), (c), 29(1), 36(3), 55(a), 56(1), (2),
57(1), (2), 64(a), (b), 65(1), (2), 71(1), 93(d), 100(1), (2), 101
Decision of the President of the EPO dated 7 September 2001
concerning documents excluded from file inspection under
Article 128(4) and Rule 93(d) EPC
European Convention on Human Rights and Fundamental Freedoms
Art. 2,6

Keyword:

"Admissibility of oppositions I and II - (yes)"

"Admissibility of appeal - (yes)"

"Invention relating to euthanasia compositions which are used for producing humane death in lower animals - whether contrary to Article 53(a) EPC - (no)"

"Inventive step - (yes) - combination of the components of the compositions not obvious"

"Absolute substance protection for the claimed compositions - whether contrary to Article 53(a) EPC - (no) or Article 84 EPC - (no) or Rule 29(1) EPC - (no)"

"Appellant's request that observations and documents submitted by the "Deutsche Gesellschaft für Humanes Sterben" be withdrawn from the file, or as an auxiliary measure, be withdrawn from the part of the file available to public inspection refused"

Decisions cited:

G 0002/88, G 0004/97, G 0001/98, G 0003/99, G 0001/03,
G 0002/03, T 0043/82, T 0036/83, T 0069/83, T 0025/85,
T 0068/85, T 0139/85, T 0296/87, T 0320/87, T 0635/88,
T 0065/89, T 0019/90, T 0483/90, T 0867/91, T 0356/93,
T 0315/03

Catchword:

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Case Number: T 0866/01 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 May 2005

Appellant:
(Opponent I)

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Respondent:
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
22 May 2001 concerning maintenance of European
patent No. 0516811 in amended form.

Composition of the Board:

Chairman: U. Oswald
Members: G. Rampold
S. Hoffmann
J. Riolo
C. Rennie-Smith

Summary of Facts and Submissions

- I. This appeal is from the interlocutory decision of the opposition division of 23 May 2000 to maintain European patent No. 0 516 811 ("the patent") in amended form. The patent is based on European patent application No. 92 902 903.1 (International application No. PCT/US91/09637), entitled "Euthanasia Compositions", which was filed on 19 December 1991 claiming a priority date of 19 December 1990.
- II. The patent as granted contained *inter alia* claims for all designated contracting states except ES and GR directed to:
- "1. A composition which comprises an aqueous solution comprising,
- (a) a cardiotoxic compound selected from the group consisting of a quinacrine salt and a chloroquine salt in a cardiotoxic amount; and
- (b) embutramide in a lethally anesthetic amount.
5. The composition of claim 4 wherein the dosage form provides between 0.15 and 0.35 ml per kg of a maximum body weight of a mammal.
8. The composition of claims 6 or 7 in a single unit dosage form containing between 0.15 and 0.35 ml per kg of body weight of a mammal.
13. The composition of any of claims 6 to 12 wherein the solution is in an injectable form and contains between 35 and 75 mg of embutramide; between 5 and 18 mg of chloroquine salt and between 0.1 and 3 mg

of water soluble inorganic salt per kg of body weight of a mammal.

14. Use of the composition according to any of claims 1 to 13 for preparing a medicament for providing euthanasia in a lower mammal."

III. Between 9 and 10 January 1997 three separate notices of opposition were filed (hereinafter referred to as oppositions I, II and III) against the patent by opponents I, II and III alleging variously

(a) that the subject-matter of the patent did not involve an inventive step (Articles 100(a) and 56 EPC) and

(b) that the publication and exploitation of the invention would be contrary to "ordre public" or morality (Articles 100(a) and 53(a) EPC).

IV. In its reply of 13 October 1997 to the notices of opposition as communicated to it pursuant to Rule 57(1) and (2) EPC, the proprietor (respondent) requested, *inter alia*, that oppositions I and II, both commenced by "multiple opponents", be rejected as inadmissible.

As regards the various objections under Articles 100(a) and 53(a) EPC to the patentability of the patent's subject-matter, the proprietor argued that the avowed use of the invention's teaching indicated in the patent ("bestimmungsgemäßer Gebrauch der erfindungsgemäßen Lehre") was the use of the claimed composition for mercy killing of lower animals and that this particular intended use did not infringe "ordre public" or morality. It was, in the proprietor's opinion not

sufficient for an objection under Article 100(a) and 53(a) EPC that the invention could also be exploited in a way that would possibly infringe some fundamental principles of morality or "ordre public".

As regards the objections under Articles 100(a) and 56 EPC, the proprietor maintained that the claimed composition exhibited unexpectedly superior properties and effects over the euthanasia agents disclosed in the closest state of the art according to citation (1) (see XII below). It argued that these properties and effects had been convincingly shown to have their origin in the distinguishing features of the invention and, accordingly, justified acknowledgment of an inventive step.

- V. In its interlocutory decision pronounced at the close of the oral proceedings on 23 May 2000, with written reasons notified on 22 May 2001, the opposition division decided to maintain the patent in amended form.

The claims of the patent as maintained by the opposition division differ from those of the patent as granted (see II above) only in that the references to "the body weight of a mammal" in dependent claims 5, 8 and 13 for all designated contracting states were amended by inserting the term "lower" before the word "mammal". The claims for the designated contracting states except ES and GR in the form maintained by the opposition division read as follows, with the amendments indicated in bold:

- "1. A composition which comprises an aqueous solution comprising,
 - (a) a cardiotoxic compound selected from the group consisting of a quinacrine salt and a chloroquine salt in a cardiotoxic amount; and
 - (b) embutramide in a lethally anesthetic amount.
2. The composition of claim 1 wherein the solution contains a ratio of embutramide to chloroquine of between 3 to 1 and 6 to 1.
3. The composition of claim 1 wherein the chloroquine salt is chloroquine diphosphate and the quinacrine salt is quinacrine hydrochloride.
4. The composition of any of claims 1 to 3 in a multiple injection form for dispensing in a syringe.
5. The composition of claim 4 wherein the dosage form provides between 0.15 and 0.35 ml per kg of a maximum body weight of a **lower** mammal.
6. The composition of claim 1 comprising
 - (a) embutramide dissolved in a water immiscible liquid solubilizing agent;
 - (b) a water soluble chloroquine salt; and
 - (c) a water soluble inorganic salt selected from an alkali metal salt and an alkaline earth metal salt other than sodium chloride.
7. The composition of claim 6 wherein the solution contains a ratio of embutramide to chloroquine of

between 3 to 1 and 6 to 1 and a ratio of embutramide to salt of between 0.01 and 0.02.

8. The composition of claims 6 or 7 in a single unit dosage form containing between 0.15 and 0.35 ml per kg of body weight of a **lower** mammal.
9. The composition of claim 6 wherein the aqueous solubilizing agent is selected from the group consisting of ethanol and denatured ethanol, the chloroquine salt is chloroquine diphosphate, the water soluble inorganic salt is potassium chloride.
10. The composition of claim 6 wherein the liquid solubilizing agent is a lower alkanol containing 1 to 3 carbon atoms.
11. The composition of claim 6 wherein sodium bicarbonate is provided in the solution as a buffer and the pH of the solution is between pH 4.5 and 7.2.
12. The composition of any of claims 6 to 11 in a single unit dosage form.
13. The composition of any of claims 6 to 12 wherein the solution is in an injectable form and contains between 35 and 75 mg of embutramide; between 5 and 18 mg of chloroquine salt and between 0.1 and 3 mg of water soluble inorganic salt per kg of body weight of a **lower** mammal.

14. Use of the composition according to any of claims 1 to 13 for preparing a medicament for providing euthanasia in a lower mammal."

Claims 1 and 14 for the contracting state ES read as follows:

- "1. A method for preparing a composition which comprises an aqueous solution comprising formulating
- (a) a cardiotoxic compound selected from the group consisting of a quinacrine salt and a chloroquine salt in a cardiotoxic amount; and
 - (b) embutramide in a lethally anesthetic amount.
14. The method according to any of claims 1 to 13 wherein the composition is prepared for providing euthanasia in a lower mammal."

Dependent method claims 2 to 13 relate to specific embodiments of the method according to claim 1 corresponding in substance to those in dependent claims 2 to 13 for the contracting states except ES and GR (see V above).

Claims 1 to 13 for the contracting state GR are identical to the method claims for ES and claim 14 is identical to claim 14 for the designated contracting states except ES (see V above).

The **description** was consequentially amended so as to replace all references to "a mammal", "the mammal" or "the animal", wherever they existed in the description of the patent as granted and whatever their context

(see page 4 of the patent as granted, lines 16, 17, 19, 20, 23, 28, 39, 55, 56, 57), with references to a or the "**lower mammal**".

VI. The reasoning of the opposition division in the interlocutory decision under appeal can be summarised as follows.

(A) The opposition division found that each of the three oppositions I, II and III fulfilled all prerequisites required under the EPC for an opposition to be admissible.

(B) As regards the oppositions under Article 100(a) in conjunction with Article 53(a) EPC to the grant of the patent, relating to euthanasia compositions, the opposition division found that, in the light of the disclosure of the claimed invention in the description, it was at least doubtful whether or not the subject-matter of claims 1 to 13 as granted was limited to the use of the claimed compositions for producing humane death solely in lower animals. The opposition division considered in the decision under appeal that the compositions as claimed in claims 1 to 13, when interpreted in the light of the description of the patent as granted, "*could be used for producing death in all kind of mammals including human beings*". The opposition division concluded therefrom that claims 1-13 as granted included subject-matter the exploitation of which would be contrary to "ordre public" and morality, within the meaning of these terms under Article 53(a) EPC, and decided not to accede to the patentee's main request that the oppositions be rejected and that the patent be maintained as granted.

(C) As regards the patent as amended *post grant* (see V above), the opposition division was in its introductory remarks of the opinion that euthanasia or mercy killing of animals was neither immoral nor contrary to "ordre public". It considered that the patent, as amended during the oral proceedings before it, no longer covered the use of the claimed compositions in humans and, accordingly, did not contain any subject-matter the exploitation of which would be contrary to Article 53(a) EPC (see especially point 3.1 of the Reasons).

(D) It found that the claimed subject-matter also fulfilled the requirements of inventive step in accordance with Article 56 EPC and decided to maintain the patent as amended.

VII. An appeal against the interlocutory decision of the opposition division was filed by the several persons forming opponent I (hereinafter "the appellant") on 23 July 2001. Within the prescribed time limits, the appellant (opponent I) paid the appeal fee and filed the statement of grounds of appeal. No other appeal was filed within the time limit set by Article 108 EPC. Opponent II, a party as of right, indicated in its letter of 4 February 2002, that it supported the arguments of opponent I. Opponent III, which is also a party as of right to the appeal proceedings, has abstained at the appeal stage from filing any comments.

VIII. The respondent (proprietor) submitted a series of counter-arguments in reply to the grounds of appeal and to the observations of opponent II. Its main

request was that the appeal be dismissed but it also filed during the written proceedings four sets of claims forming its main and first, second and third auxiliary requests.

IX. In a communication dated 30 September 2004, the parties were duly summoned to oral proceedings pursuant to Rule 71(1) EPC. By their representatives' letters of 28 February 2005 and 8 April 2005 respectively, opponents II and III (parties to the appeal by virtue of Article 107, second sentence, EPC) informed the board that they would not be present or represented at the oral proceedings.

X. In a further communication dated 15 April 2005, the board invited the respondent to demonstrate by appropriate evidence that an unequivocal, generally accepted meaning exists in the relevant art for the expression "lower mammal" used in the patent. In its reply of 4 May 2005, the respondent submitted that *"in the pharmaceutical art the expression "lower animal" always means "less than human", i.e. mammals except humans."* In support of this submission it relied on the documents US-B-6 277 415, US-B-664 9360, US-B-6 863 536, US-B-6 194 387, US-A-6 083 979, US-A-6 030 969 and US-A-5 612 350.

XI. Oral proceedings took place on 11 May 2005 attended by the appellant (opponent I) and the respondent (proprietor).

In addition to its main request that the appeal be dismissed, four auxiliary requests of the respondent were on file at the end of the oral proceedings.

XII. In the present decision reference is made to the following documents filed by the parties:

- (1) Veterinary Pharmacology and Therapeutics, edited by N. H. Booth et al, Iowa State University Press/Ames, USA, 6th edition, 1988, pages 1143-1148;
- (2) M. J. Ellenhorn et al, Medical Toxicology, Diagnosis and Treatment of Human Poisoning, Elsevier 1988, pages 341-345;
- (3) T. A. Don Michael et al, "The effects of acute chloroquine poisoning with special reference to the heart", American Heart Journal, vol. 79, no. 6, 1970, pages 831-842;
- (4) Declarations I and II by Dr Taylor submitted by the respondent during opposition proceedings with its letter of 13 October 1997;
- (5) Veterinary Pharmaceuticals and Biologicals, Veterinary Medicine Publishing Group, 9th edition 1995/96, pages 261-262, 371-372, 656 and product category index page 63.

Reference is also made in this decision to the following legal texts:

- Mellulis in Benkard, Europ. Patentübereinkommen, Beck'sche Kurz-Kommentare 2002 (hereinafter referred to as Benkard/Mellulis);
- Bruchhausen in Benkard, Patentgesetz, Gebrauchsmustergesetz, 8. Auflage, München 1988 (hereinafter referred to as Benkard/Bruchhausen);

- Singer/Lunzer, European Patent Convention, Sweet & Maxwell, London 1995 (hereinafter referred to as Singer/Lunzer);
- Commentaries by Schatz and Kroher in Singer/Stauder, European Patent Convention, third edition, Carl Heymanns Verlag 2003, Vol. 1 (hereinafter referred to as Singer/Stauder with further reference to the author);
- Moufang, Europäisches Patentübereinkommen, Münchner Gemeinschaftskommentar, Carl Heymanns Verlag, 15. Lieferung, April 1991, Art. 53, Ausnahmen von der Patentierbarkeit (hereinafter referred to as MGK/Moufang);
- J. Busche, "Öffentliche Ordnung und gute Sitten als allgemeine Schranken für die Erteilung von Patenten" GRUR Int. 1999, 301-306 (hereinafter referred to as Busche GRUR Int. 1999, 301).

XIII. The arguments presented by the appellant and opponent II (as a party to the appeal by virtue of Article 107, second sentence, EPC) in the appeal proceedings, in so far as they are relevant to the present decision, are summarised below. In the case of the appellant, who filed written submissions and attended the oral proceedings, the following summary reflects both the written and oral submissions.

*Re: Inventive Step - Articles 100(a) and 56 EPC;
arguments of the appellant*

[01] The appellant disputed the finding that the claimed subject-matter involved an inventive step as required by Article 56 EPC. In its view, the skilled person arrived at the claimed composition without

inventive effort by simply substituting a quinacrine salt or a chloroquine salt for the active component mebezonium diiodide present in the euthanasia solution "T-61" disclosed in citation (1) and discussed in detail in the introductory portion of the patent specification. In the appellant's opinion, this substitution would be obvious to those skilled in the art because the cardiotoxic effect of chloroquine salts had already been described in citations (2) and (3).

[02] The appellant considered that the present case was entirely comparable to those decided in decisions T 69/83 (OJ EPO, 1984, 357, especially Reasons point 7) and T 296/87 (OJ EPO, 1990, 195, especially Reasons point 8.4). In this context it referred to Singer/Stauder/Kroher, EPC, third edition, Carl Heymanns Verlag 2003, Vol. 1, Art. 56, Rdnr. 100, where it is stated that *"according to the case law of the boards of appeal, unforeseen beneficial effects do not, however, lead to recognition of inventive step if the state of the art imposes the found solution on the skilled person for at least a substantial part of the problem. The unexpected solution of a sub-problem that comes easily to the skilled person when applying obvious and scheduled measures, is not inventive."*

The appellant concluded therefrom that the results of the experiments reported in the declarations (4), even if they were considered as surprising and unforeseeable could not, in the present case, contribute to the acknowledgment of an inventive step. It argued that, on a euphemistic approach, euthanasia (i.e. providing humane death) could possibly be considered in the present case as a sub-problem of the general problem

underlying the patent which was, in the appellants' opinion, termination of life in general. It was observed by the appellant that the severe cardiotoxicity of chloroquine and quinacrine salts and their application to humans and animals was already well known in the state of the art according to (2) and (3) and suggested to those skilled in the art the excellent suitability of these substances for solving the problem underlying the patent of terminating life (i.e. killing) of all living beings in general, both humans and animals. With reference to the decisions cited above, the appellant argued that the solution of the sub-problem euthanasia, even if it was solved in an unexpectedly beneficial way, could not contribute to an inventive step because the unexpected solution of this sub-problem was a genuine additional benefit that came easily to the skilled person since the known lethal cardiotoxicity of chloroquine and quinacrine salts imposed the use of this substance on the skilled person faced with the solution of the general problem of terminating life.

Re: Exception to patentability under Article 53(a) EPC ("ordre public" and morality) - arguments of the appellant

[03] It was recalled by the appellant that the opposition division relied in the decision under appeal on decisions T 320/87 (OJ EPO, 1990, 71), T 19/90 (OJ EPO 1990, 476) and T 356/93 (OJ EPO, 1995, 545) in support of its opinion that exclusions from patentability under Article 53(a) EPC must be construed narrowly.

[04] As regards decision T 320/87 (*loc. cit.*) the appellant was of the opinion that this decision was only concerned with the exclusion from patentability in Article 53(b) EPC. Moreover, it dealt with a technically borderline case and was thus in the appellant's opinion not relevant to the interpretation of Article 53(a) EPC which in its view regulated the exclusion from patentability of ethically borderline cases.

[05] In its written and oral submissions, the appellant also referred to decision T 19/90 (*loc. cit.*) and quoted the following passage from point 5 of the Reasons: *"The decision as to whether or not Article 53(a) EPC is a bar to patenting the present invention would seem to depend mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other. It is the task of the department of first instance to consider these matters in the context of its resumed examination of the case."*

The appellant concluded therefrom that, in contrast to Article 53(b) EPC, the correct application of Article 53(a) EPC ruled out "a priori" a restrictive interpretation of the exception to patentability under this provision but required a careful weighing up of the details of each particular case to arrive at a clear decision for or against. Once so accepted, it was in the appellant's opinion irrelevant whether the exclusion was interpreted narrowly or broadly since the opposition division or the board had to establish

carefully in each particular case the European public's moral approach to the invention.

[06] The appellant then discussed decision T 356/93 (*loc. cit.*) and, in particular, the following passage from point 8 of the Reasons: "*From the historical documentation relating to the EPC it appears that the view according to which "the concept of patentability in the European patent law must be as wide as possible" predominated (see document IV/2071/61-E, page 5, point 2, first paragraph). Accordingly, the exceptions to patentability have been narrowly construed, in particular in respect of plant and animal varieties...."*

The appellant argued that the general guidance given in that historical document as to the limit of the concept of patentability in European patent law, namely "as wide as possible", was compatible but not necessarily identical with the general legal principle that exclusions from patentability must be construed narrowly. The restrictive interpretation of exclusions from patentability was in the appellant's opinion justified in cases where the subject-matter to be excluded from patentability on the basis of a legal provision could be defined exactly. This was true of the exclusion in Article 53(b) EPC, the legal background to which was the clear distinction "*a priori*" between subject-matter eligible for patent protection and subject-matter eligible for alternative industrial property rights such as plant variety protection. The exclusion in Article 53(a) EPC differed fundamentally from this in that it presupposed that, in each single case, all the features and their functions

as disclosed in the teaching according to the patent had to be clarified and to be taken into careful consideration.

[07] On the basis that, in the appellant's opinion, only the restrictive interpretation might be considered as sensible and conducive to rational application of Article 53(a) EPC, it rejected the respondent's argument that a possible use of the claimed invention which was morally acceptable and thus allowable should prevail over another possible use which was immoral and thus unallowable under Article 53(a) EPC. In this context the appellant argued that, in contrast to Article 53(b) EPC, the correct application of Article 53(a) EPC ruled out such a restrictive interpretation of the exception to patentability, with the consequence that the mere possibility of a misuse contrary to "ordre public" or morality should in itself be regarded as sufficient "indicative evidence" of the immorality of an invention.

[08] In the appellant's view the only relevant criterion for the application of Article 53(a) EPC was the existence of any kind of particularly serious substantive reasons for the immorality of the invention and their adequate substantiation. This was, in the appellant's opinion clearly expressed in headnote I of decision T 356/93 (*loc. cit.*): *"Under Article 53(a) EPC, inventions the exploitation of which is likely to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public" (see point 5 of the Reasons). However, a decision in this respect presupposes that the threat to the*

environment be sufficiently substantiated at the time the decision is taken by the EPO."

[09] The appellant also argued that the opposition division had correctly relied on the following guidance and advice from the Guidelines (C-IV, 3.1) for the application of Article 53(a) EPC to the present case: *"A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that it is the case, objection should be raised under Article 53(a) EPC."*

In the appellant's opinion, the opposition division had carefully and correctly considered all the relevant circumstances of the case and, by using the above test, had reached in the decision under appeal (see Reasons, end of point 2.21) the entirely correct conclusion in respect of the patent as granted, namely *"that the subject-matter at issue is also contrary to morality within the meaning of Article 53(a) EPC"*.

[10] However, the fact could not be ignored that, in spite of the amendments to the claims and the description in the auxiliary request filed during oral proceedings, the opposition division had decided to maintain a European patent which from a formal and a substantive point of view did not comply with the basic requirements of the Convention. In this context it was recalled by the appellant that the most significant passage on this point in the contested decision was that found in paragraph 2.11 of the Reasons, where it was stated as follows: *"Therefore, when interpreting*

claims 1-13 in the light of the description, the opposition division comes to the conclusion that the compositions could be used for producing death in all kind of mammals, including human beings."

In the appellant's opinion, this finding was entirely correct and could not be modified or altered by simply inserting the expression lower before the terms "a mammal" or "an animal" on page 4 of the patent description.

[11] The appellant went on to say that, even taking account of the amendments, the stated purpose of the invention remained the provision of "euthanasia compositions" and nothing else. This was clear from the paragraph "Objects" on page 4 of the description which did not, even after the amendment, contain any limitation of the use of these compositions to euthanasia in lower animals. Moreover, the reference at page 3, lines 57-59, to the toxicity of chloroquine and quinacrine in humans clearly implied their application in lethal doses to humans as well.

[12] The appellant mentioned that while the term "euthanasia" in the English language comprised acts of killing of both humans and animals, in the German language the term "euthanasia" was essentially limited to humans. The corresponding term for ending the life of animals was mercy killing ("Einschläfern"). The difference between the terms "euthanasia" and "killing" was merely one of wording but not of substance. The task which the invention in the patent set out to meet consisted therefore in the provision of compositions for killing living species (humans and animals). It was

not apparent to the appellant how the term "euthanasia compositions" could be replaced, without contravention of Article 123(2) EPC, by another expression which excluded the application of the compositions to humans.

[13] The opposition division's finding that the European patent as granted and, accordingly, the European patent application as published contained subject-matter which was to be regarded as contrary to "ordre public" or morality meant that, as early as the time of publication, there existed a bar to patentability under Article 53(a) EPC. This deficiency could not be remedied after publication by the later deletion of the immoral subject-matter. As a consequence of this, the European patent application had to be refused and, since this had been overlooked in error, the patent had to be revoked in opposition proceedings.

[14] Finally, the appellant argued that the animal tests underlying the patent would be considered as cruel. In this case, weighing up of the suffering of animals against the possible benefit achieved by the invention would clearly demonstrate a violation of Article 53(a) EPC, because some alleged but not even properly demonstrated benefits did not outweigh the negative aspects such as the suffering of animals.

Re: Exception to patentability under Article 53(a) EPC ("ordre public" and morality)- arguments of opponent II, party to the appeal proceedings as of right

[15] It was observed by opponent II that, in accordance with Article 69 EPC and its protocol, the scope of protection conferred by the patent was determined by the claims and that the description and the drawings may *inter alia* be employed "*for the purpose of resolving an ambiguity found in the claims*". Accordingly, claims 1-13 of the patent as maintained covered the application of the claimed toxic composition in human beings.

The respondent's statement of 11 December 1998 "*that it will use the claimed composition only in animals and not in humans*" did not change this. Having regard to the legal principle "*venire contra factum proprium*" this statement was a unilateral declaration by the proprietor addressed only to the other parties to the present proceedings and was thus effective, if at all, only "*inter partes*", *i.e.* between the parties to the present proceedings. This "*inter partes*" effect was, however, insufficient to remove "*erga omnes*" the immorality of the protected subject-matter of claims 1 to 13, as it would be necessary to comply with Article 53(a) EPC. That could only be achieved by a suitable limitation of the patent.

[16] Opponent II also repeated that Article 53(a) EPC excluded the grant of a European patent in respect of inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality. The European Convention on Human Rights (ECHR) should be used in the present case to interpret the unspecific legal term "*ordre public*" in Article 53(a). Article 2 ECHR, which stated that "*no one shall be deprived of his life intentionally*", guaranteed the protection of

everyone's right to life. In the present case the grant of the European patent for euthanasia compositions according to claims 1 to 13 created at least a real risk to the integrity and protection of life guaranteed in Article 2 ECHR and was therefore unacceptable under the terms of Article 53(a) EPC.

[17] In the opinion of opponent II, the grant of a patent rewarded the particular intellectual and socio-ethic achievement of the inventor by conferring on him a monopoly right. The claimed compositions in the patent represented toxins which could be only used for one sole purpose, namely to terminate animal and human life. By the grant of this patent to the proprietor, the EPO as the relevant international authority rewarded the proprietor and the inventor by conferring on them a monopoly right for the creation and provision of a toxin for destroying human life. This was clearly against the principles of Article 2 ECHR, which obliged the legislator and general laws and also any international authority such as the EPO to protect human life.

[18] In point 2.17 of its decision the opposition division had in effect approved the foregoing observations of opponent II. However, it had nevertheless drawn the fundamentally wrong conclusions by allowing the unlimited product claims as granted because the modification of the description had no limiting effect on the scope of protection of the composition claims. In accordance with the consistent case law of the boards of appeal (see e.g. T 43/82 of 16 April 2004 and T 36/83, OJ EPO 1986, 295), the protection of chemical products in general was not

based on purpose-limited product claims which conferred product protection limited only to specific uses indicated in the patent but was rather based on absolute product protection.

XIV. The arguments of the respondent as submitted in writing and during the oral proceedings, in so far as they are relevant to the present decision, can be summarised as follows.

Re: Admissibility of Oppositions

[19] As regards the admissibility of the oppositions, the respondent disagreed with the opposition division's view in the decision under appeal that each of the three oppositions fulfilled all the requirements of the EPC for an opposition to be admissible. It argued that, if an opposition were to be found inadmissible (which was still possible in appeal proceedings), the opponent in question could be neither appellant nor party as of right.

[20] With reference to the file history, it was recalled by the respondent

- (a) that opposition I designated the "Europäische Arbeitsgemeinschaft Mut zur Ethik", represented by Dr A. Knötgen, and several other organisations and also the natural persons listed in Annex I as joint opponents and identified Dr Mylaeus as common representative;
- (b) that the document giving notice of opposition had not been signed and that the persons forming opponent I were thus invited by a first communication of the opposition division dated

20 January 1997 to remedy that deficiency within a period of two months; and

- (c) that in reply to the opposition divisions's communication, Dr Knötgen filed on 3 March 1997, with her letter dated 16 February 1997 a copy of the notice of opposition signed by her on behalf of the opponents.

[21] The respondent complained that the communication dated 20 January 1997 had not been sent to the respondent's representatives. As was apparent from a file inspection, in a further communication dated 14 August 1998 Dr Knötgen was requested by the opposition division

- (a) to clarify within a term of 2 months on whose behalf she had signed the notice of opposition; and
- (b) to indicate any official capacity in which she had done so.

The opposition division had also stated in that communication

- (c) that Dr Knötgen could only act as, or appoint, a common professional representative or legal practitioner for those persons who had duly signed the notice of opposition;
- (d) for this reason, the legal practitioner authorised by her could act only on behalf of those persons who had duly signed the notice of opposition; and
- (e) since it had not been entirely clear from the earlier communication of 20 January 1997 that each party had to sign the notice of opposition, for reasons of good faith, the opposition division again requested those parties named as opponents in the notice of opposition and whose signature

was not yet on the file to supply the missing signatures within a period of two months.

[22] The respondent summarised the reasoning of the opposition division in the decision under appeal as to the admissibility of opposition I as follows:

- (a) the opposition division did not see a reason to depart from the existing practice of the EPO to allow a joint opposition with payment of one opposition fee;
- (b) since Dr Knötgen had indicated in the notice of opposition that she had acted either on behalf of the "Europäische Arbeitsgemeinschaft Mut zur Ethik" or in her own name, the opposition division concluded that there had been an indication as to the possible identity of at least one of the joint opponents;
- (c) in view of her letter dated 10 December 1998, it had furthermore been clarified that Dr Knötgen was opponent in the present opposition, but the "Europäische Arbeitsgemeinschaft Mut zur Ethik" was not;
- (d) even if the view was taken that Dr Knötgen could not take part in the proceedings, the opposition would still be admissible since there were joint opponents whose identity had been clearly indicated in the notice of opposition;
- (e) finally, all parties who had filed their signature within the time limit set by the opposition division in their communication of 14 August 1998, were to be considered as members of the joint opponent I.

[23] The respondent disagreed with the opposition division for the following reasons. The opposition division's first communication of 20 January 1997 (although not notified to the respondent's representatives) informed opponent I about certain deficiencies in the notice of opposition; had invited opponent I to sign the notice of opposition, and to file the authorisation of its representative within the time limit (two months) provided for in Rule 36(3) EPC and in the form used for the invitation; and had expressly drawn the attention of opponent I to the legal consequences of Rule 36(3), 3rd sentence, EPC which provided that if a document (in this case, the notice of opposition) was not signed in due time, it was deemed not to have been filed.

[24] The respondent concluded that, from a legal point of view, the opposition division could not set aside the consequences of missing the time limit set in the communication of 20 January 1997 for filing the missing signatures by simply issuing the further communication of 14 August 1998 containing a further invitation to file the missing signatures within a new time limit set in the later communication.

[25] The respondent therefore requested that opposition I be found inadmissible.

Re: Admissibility of the Appeal

[26] As regards the admissibility of the appeal, the respondent argued that, even if the board concurred with the findings of the opposition division concerning the admissibility of all three oppositions, the appeal

filed on 23 July 2001 must nevertheless be dismissed as inadmissible. In particular, the respondent argued:

- (a) that a formal appeal had been filed by Dr Mylaeus who designated himself in the notice of appeal as "representative of the opponents" ("Vertreter der Einspruchsführer"), without identifying such as members of the appellant by giving their names and addresses as required by Rule 64(a) EPC;
- (b) that in the notice of appeal it was merely indicated that an opposition had been filed on 9 January 1997;
- (c) that the identity of the appellant was uncertain since both oppositions I and II had been filed on 9 January 1997; and
- (d) that the persons comprising the appellant for whom Dr Mylaeus acted as a common representative were accordingly not identifiable in the notice of appeal.

[27] The respondent then noted that this lack of identity of the appellant could not be remedied by invitation under Rule 65(2) EPC since only deficiencies and omissions in information concerning the appellant can be remedied in that manner, whereas the identity of the appellant must be known and verifiable from the outset of proceedings. This was confirmed in decision T 25/85 (OJ EPO 1986, 81). That decision, although relating to the question of whether or not the lack of identity of an opponent could be remedied by invitation under Rule 56(2) EPC, was nevertheless relevant to the present case because the wording of Rule 56(2) EPC and Rule 65(2) EPC was identical. Point 11 of the Reasons in decision T 25/85 (*loc. cit.*) referred explicitly to

appeals by stating: "A comparable situation also exists when an appeal is filed. Here too, as can be inferred from Articles 106(1), 107 and 108 EPC, the appellant must be identified by the time the period for appeal expires. On the other hand, details of this designation may under Rules 64(a) and 65 EPC, which are worded identically to Rules 55(a) and 56 EPC, be given later. In the case of appeals, however, the decision of the department of prior instance being appealed against is a means of identification. Nevertheless, an appeal can also fail because the appellant cannot be identified."

[28] On the basis of the above considerations, the respondent requested that the appeal filed on 23 July 2001 be considered inadmissible.

Re: *Inventive Step (Article 56 EPC)*

[29] The respondent argued that the problem underlying the present patent was the provision of euthanasia compositions for lower animals which eliminated the presence of a noticeable heartbeat encountered with the known euthanasia solution "T-61" disclosed in citation (1). This citation, which was considered by the respondent to be the closest prior art, summarized the criteria which an agent should ideally satisfy to qualify as a euthanising agent. According to document (1), "T-61" was a mixture of γ -hydroxybutramide, tetracaine, mebezonium and an aqueous solution of dimethylformamide. The composition of claim 1 of all requests differed from "T-61" in that it contained a quinacrine salt or a chloroquine salt instead of mebezonium diiodide and did not use tetracaine and dimethylformamide.

[30] Citations (2) and (3) described the effects of acute chloroquine poisoning, in particular the cardiotoxic effects of chloroquine. They did not, however, teach or suggest that chloroquine was a suitable compound for euthanasia. In fact, citation (1) clearly taught away from using cardiac drugs for euthanasia (see page 1148, left column, paragraph 2).

[31] As demonstrated by the declarations (4) of one of the inventors filed during the opposition, the use of chloroquine alone at lethal dosages lead to unacceptable side effects. On the other hand, the examples in the patent and the declarations (4) showed that the claimed compositions solved the problem underlying the patent. An additional advantage over "T-61" resided in the fact that the claimed composition did not use tetracaine which lead to stiffening.

[32] Therefore, it was in the respondent's opinion not obvious from the prior art to use a chloroquine or quinacrine salt alone and even less obvious to use any of these salts in combination with embutramide in a euthanasia composition. Consequently, the claimed subject matter involved an inventive step.

Re: Exception to patentability under Article 53(a) EPC ("ordre public" and morality)

[33] The respondent observed that claim 1 of the patent as maintained by the opposition division related to a composition comprising an aqueous solution of two compounds, namely a cardiotoxic compound selected from a quinacrine salt and a chloroquine salt in a

cardiotoxic amount and embutramide in a lethally anesthetic amount. Claim 14 related to the use of said composition for providing euthanasia in a lower mammal. Only this particular intended use for the claimed composition was described throughout the patent specification. As clearly and unequivocally explained in citation (1), the term "euthanasia" meant "*the humane or mercy killing of animals to alleviate suffering.*"

[34] The respondent argued that, according to conventionally accepted standards of European culture, mercy killing of animals in order to alleviate suffering was neither immoral nor against "ordre public" and hence did not contravene Article 53(a) EPC. It was irrelevant for the purposes of patentability whether the invention could also be used in a manner which might be considered to be immoral or against "ordre public". In the respondent's opinion, its view was in clear accordance with the practice and case law of the EPO.

In this context, the respondent went on to say that any chemical composition could be misused, e.g. for killing someone, if only the dosage was high enough. Nevertheless the EPO generally granted patents for chemical compositions, without normally requiring any kind of limitation in the claims to the use of such compositions in a specific dosage or for a specific purpose.

[35] The respondent referred to decision T 356/93 (*loc. cit.*) which defined the concepts of "ordre public" and morality. It was pointed out in this decision that

exceptions to patentability had to be narrowly construed and that this applied to Article 53(a) EPC. The respondent quoted the following passage from point 17.1 of the Reasons: *"Like any other tool, plant genetic engineering techniques can be used for constructive or destructive purposes. It would undoubtedly be against "ordre public" or morality to propose a misuse or a destructive use of these techniques."* This demonstrated clearly that the particular purpose of the invention or its intended use was decisive for establishing whether or not its exploitation would be contrary to public order or morality.

[36] This view was confirmed, in the respondent's opinion, by decision G 1/98 (OJ EPO 2000, 111) of the Enlarged Board of Appeal. Although this decision mainly dealt with the exception to patentability under Article 53(b) EPC, it contained a pertinent statement under item 3.3.3 with regard to Article 53(a) EPC which reads:

"It may be helpful to look at the neighbouring exclusion in Article 53(a) EPC and ask what the situation would be if a claim were to cover something immoral or contrary to "ordre public". Suppose that a claimed invention defined a copying machine with features resulting in an improved precision of reproduction and suppose further that an embodiment of this apparatus could comprise further features (not claimed but apparent to the skilled person) the only purpose of which would be that it should also allow reproduction of security strips in banknotes strikingly similar to those in genuine banknotes. In such a case,

the claimed apparatus would cover an embodiment for producing counterfeit money which could be considered to fall under Article 53(a) EPC. There is, however, no reason to consider the copying machine as claimed to be excluded since its improved properties could be used for many acceptable purposes."

The respondent argued that this decision of the Enlarged Board of Appeal confirmed the present practice of the EPO to only exclude a claim from patentability under Article 53(a) EPC if the claimed subject matter could not be used otherwise than in a way which is contrary to "ordre public" or morality. Since the claimed composition was used for mercy killing of animals to alleviate suffering, it served an "acceptable purpose" in the sense of decision G 1/98 (*loc. cit.*) and, thus, did not contravene Article 53(a) EPC.

[37] Finally, the respondent noted, with reference to decision T 356/93 (*loc. cit.*), that the right to exploit the invention was not unconditional, but may be restricted by other laws and regulations. In that decision the board stated that there is *"an increasing number of other authorities and bodies, in particular regulatory authorities and bodies, whose function is inter alia to ensure that the exploitation of a given technology, regardless of whether it is protected by a patent or not, takes place within the regulatory framework provided by laws, international treaties, administrative provisions, etc. . . . The assessment of the hazards stemming from the exploitation of a given technology is one of the important duties of such regulatory authorities and bodies."*

XV. The appellant requested that the decision under appeal be set aside and that the patent be revoked and that the observations and documents submitted by the "Deutsche Gesellschaft für Humanes Sterben" be withdrawn from the file, or as an auxiliary measure, that these documents and observations be withdrawn from the part of the file available to public inspection.

The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the sets of claims in

- the first auxiliary request filed during oral proceedings or
- the second to fourth auxiliary requests filed as the first and second auxiliary requests on 13 March 2002 and as the third auxiliary request on 14 February 2005.

Reasons for the Decision

1. *Admissibility of the Oppositions - introductory remarks*

1.1 The respondent objected at first instance to the admissibility of oppositions I and II, both commenced by "multiple opponents". In the interlocutory decision under appeal, the opposition division found that each of the three oppositions filed in the present case (oppositions I, II and III) fulfilled all the admissibility requirements of the EPC.

1.2 As is apparent from XIV [19] - [25] above the respondent, both in its reply of 13 March 2002 to the statement setting out the grounds of appeal and at the hearing before the board, disagreed with the finding of the opposition division and maintained and repeated its objections to the admissibility of oppositions I and II. This is therefore the first point to be decided.

1.3 It is a principle firmly established by board of appeal case law that the admissibility of oppositions can be questioned and must be checked *ex officio* at every phase of the opposition and any ensuing appeal proceedings (G 4/97, OJ EPO 1999, 270, Order, paragraphs 1 and 2; and see generally "Case Law of the Boards of Appeal of the EPO", 4th edition 2001, pages 462 to 463).

Admissibility has to be judged on the basis of the content of the notice of opposition as filed, taking account of additional documents filed before the expiry of the opposition period in so far as they remedy any deficiency fatal to the admissibility. Such a defect cannot be remedied outside the opposition period (Rule 56(1) EPC, in fine).

Admissibility of Opposition I

1.4 Opposition I was originally filed by Dr Anita Knötgen et al in the name and on behalf of

- (i) the "Europäische Arbeitsgemeinschaft Mut zur Ethik" (which itself consisted of 28 unidentified organisations and an unknown number of unidentified individual persons); and
- (ii) several other organisations and individuals, and

(iii) a certain number of individual persons listed and duly identified by their names and addresses in Annex No. 1 to the notice of opposition.

(See notice of opposition dated 9 January 1997, pages 1-2: *"Namens und im Auftrag der Europäischen Arbeitsgemeinschaft Mut zur Ethik und weiterer Organisationen sowie der im Beiblatt (Anlage Nr. 1) angeführten Personen wird hiermit gegen das vorstehend bezeichnete Europäische Patent Einspruch gem. Art. 99 EPÜ erhoben. Die Europäische Arbeitsgemeinschaft "Mut zur Ethik" ist ein ehrenamtlich getragener, interdisziplinärer Verbund mit 28 unabhängigen Organisationen und zahlreichen Einzelpersonlichkeiten"*).

- 1.5 The essence of the opposition division's reasoning in the decision under appeal in favour of the admissibility of opposition I was as follows (see especially Reasons, points 1.2 and 1.3):

"The notice of opposition which was signed by Dr Anita Knötgen indicated that she had acted on behalf of the Europäische Arbeitsgemeinschaft "Mut zur Ethik" or in her own name. Therefore, there was an indication as to the possible identity of one party of the joint opponents. In response to the opposition division's communication dated 14 August 1998, Dr Anita Knötgen declared in due time in her letter dated 10.12.98 (10 December 1998) that she had filed the opposition in her own name. In view of this declaration the Europ. Arbeitsgemeinschaft "Mut zur Ethik" is not opponent in the present opposition proceedings but Dr Anita Knötgen is. However, even if the view was taken that Dr Anita Knötgen could not take part in the proceedings, the

opposition should still be considered as admissible since there are joint opponents whose identity was clearly indicated in the notice of opposition <.....>.

As pointed out in the opposition division's communication of 14 August 1998, some but not all parties named as opponents in the notice of opposition and the attached list had duly signed the notice of opposition. If the notice of opposition indicates that it was filed by more than one person each party or his representative, duly authorised according to Articles 133, 134 and Rule 101 EPC, must have signed the notice of opposition giving rise to his participation. Otherwise the party cannot take part in the proceedings. Since it did not clearly follow from the EPO's communication of 20 January 1997 that each party had to sign the notice of opposition, in application of the principle of good faith the opposition division requested again the signatures of the parties named in the notice of opposition and in the attached list as opponents whose signature was not yet present in the file. All parties who have signed the notice of opposition as such or who have filed subsequently their signature in due time are therefore considered as joint opponents of opposition I."

- 1.6 In decision T 635/88 (OJ EPO 1993, 608, point 2 of the Reasons) the board clearly stated that "any person" in Article 99 EPC is to be construed in line with Article 58 EPC as meaning: (a) any natural person, (b) any legal person or (c) any body equivalent to a legal person by virtue of the law governing it. The legal personality of a named entity under the EPC is decided

on the same basis as before national courts, namely the capacity to sue or to be sued in its own name and on its own account. The fact that "any person" has to be interpreted in line with Article 58 EPC results in particular from Rule 55(a) EPC which refers directly to Rule 26(2)(c) EPC which lists the same entities. The Enlarged Board said in G 3/99 (OJ EPO 2002, 347, Reasons, point 9):

"As regards an opposition filed in common by a plurality of persons, each of the common opponents must be either a natural person, or a legal person, or a body equivalent to a legal person by virtue of the law governing it, or a combination thereof."

- 1.7 With reference to the opposition division's reasoning in the contested decision (see 1.5 above), the board cannot concur with the opposition division's conclusion that, in addition to the group of individuals, all other parties (persons) who duly signed the notice of opposition are to be considered as joint opponents in the present case. Even if the opposition division concluded that the filing of opposition I in the name and on behalf the "Europäische Arbeitsgemeinschaft Mut zur Ethik" had not given it party status, the opposition division did not make any inquiries as to the legal status of the various other organisations named as common opponents in the notice of opposition, e.g. "Niederländischer Ärzteverband" (NAV), "World Federation of Doctors Who Respect Human Life", "Europäische Ärzteaktion", "Pro Vita" and "Bürgerinstitut Prag". Following G 3/99 (*loc.cit.*), while any of these organisations may not be a legal person or "body equivalent to a legal person" under the

national law of a contracting state, it might be a "combination" of legal, or legal and natural persons.

Further, the opposition division failed to make any attempt to clarify whether or not e.g. Dr med. Krijn J. P. Haasnot had signed the notice of opposition in his capacity as representative of the Niederländische Ärzteverband or Dr med. Karel Gunning in his capacity as representative of the World Federation of Doctors Who Respect Human life. As they are President and Vice-President respectively of the organisations which they apparently represent and as both signed the notice of opposition adding the name of their respective organisation, these signatures could have been made either on behalf of those organisations or by the natural persons characterized by their membership of these organisations. Since the opposition division omitted to clarify the legal status of the various organisations named as common opponents and of the persons acting on behalf of those organisations, the decision under appeal is defective in this respect.

- 1.8 The board has to decide who are the persons involved in the opposition proceedings on its own motion at any stage of the proceedings (see 1.3 above). In point 11 of the Reasons of its decision G 3/99 (*loc.cit.*) the Enlarged Board said: *"Where, as in the referred case, it is doubtful whether the opposition is filed on behalf of a body which enjoys legal personality in its own right, or on behalf of several natural persons acting in common, the opposition division shall invite the opponents to establish that the body is a legal person or an equivalent thereto. If this is not established, the opposition is to be considered as*

having been filed on behalf of the several natural persons as common opponents."

- 1.9 The board adopts that principle in the present case where the opposition was filed neither by a body which enjoys legal personality in its own right nor by natural persons acting in common but by a combination of natural persons and legal persons (or bodies equivalent to legal persons by virtue of the law governing it), all or some of them acting in common (see 1.4 above).

The Enlarged Board also said in G 3/99 (*loc.cit.*) - see Order, paragraph 3: *"In order to safeguard the rights of the patent proprietor and in the interests of procedural efficiency, it has to be clear throughout the procedure who belongs to the group of common opponents or common appellants. If either a common opponent or appellant (including the common representative) intends to withdraw from the proceedings, the EPO shall be notified accordingly by the common representative or by a new common representative determined under Rule 100(1) EPC in order for the withdrawal to take effect."*

As in the present case it has not been established whether the common opposition I has been filed on behalf of bodies which enjoy legal personality in their own right, or bodies equivalent to legal persons by virtue of their governing law, it appears in the board's view justified to consider opposition I as having been filed in common at least by the individuals allegedly acting for these bodies and the other individuals listed in the notice of opposition. This

group of 16 individuals is clearly and unequivocally identified by name, address, date of birth and nationality in Annex 1 to the notice of opposition filed on 9 January 1997 and corrected on 10 January 1997, namely the persons set out below:

"Dr. Anita Knötgen
Prof. Dr. Dr. Brantner
Prof. Dr. Gudrun Kammasch
Dr. med. Karel Gunning
Dr. med. Dr. h.c. Siegfied Ernst
Dr. med. Felix Berger
Michaela Frelóva
Prof. Dr. Horst Seidl
Prof. Dr. med. Hans-Bernd Wuermeling
Dr. Andreas Mylaeus
Dr. med. Sabine Schulte-Holtey
Dr. med. Krijn J. P. Haasnot
Dr. Alfons Adam
Dr. Stefan Poledna
Julia Schätzle
Peter Lerch".

- 1.10 The board is aware that the patentee/respondent is entitled to know who is attacking it. In the present case it may not in fact feel very strongly about the difference between on the one hand a group of individuals and on the other hand that group plus various sundry named organisations but it none the less has the right to know - for example, if an order for costs was made against the "group opponent", then the larger the group, the greater might be the respondent's chance of actually recovering those costs. Since, however, neither in writing nor at the oral proceedings

the respondent objected to or disagreed with the board's view regarding the joint members of common opponent I, no further consideration of this appears to be necessary or appropriate.

- 1.11 There must in all cases of a "multiple opponent" be a common representative (Article 133(4) EPC and Rule 100 EPC) and only that common representative is entitled to act in the opposition proceedings on behalf of all the members of the "multiple opponent". Consequently, neither an individual who is not the common representative nor a subgroup of those making up the "multiple opponent" is allowed, other than by their common representative, to act or intervene on his own or on behalf of one or more or all of the other individuals. Thus, only the common representative is entitled to sign the filed documents (Rule 100 EPC and Rule 36(3) EPC), the signature of other individuals not being required - see G 3/99 (*loc. cit.*), especially Reasons, point 14.

Since a procedural act performed by a non-entitled person is treated by the EPO in the same way as a missing signature (T 665/89 of 17 July 1991, see Reasons, point 1.4), each member of a "multiple opponent" or any other person acting on his behalf can perform such an act to avoid missing a time limit, provided the deficiency is remedied within a further time limit set in a communication under Rule 36(3) EPC notified to the common representative and sent for information to the non-entitled person who performed the act. The deficiency can be remedied if the procedural act is signed by the common representative - see G 3/99 (*loc. cit.*), especially Reasons, point 20.

1.12 In the decision under appeal, the opposition division presumed Dr A. Knötgen to be the common representative since she was the opponent first named in the notice of opposition (Rule 100(1) EPC). In doing so, it did apparently not pay attention to the fact that one member of the multiple opponent, namely Mrs Michaela Frelóva residing in the Czech Republic, did not, at the time of filing the opposition, have her residence or principal place of business within the territory of one of the contracting states and was also not a national of a contracting state. According to Article 133(2) EPC she had to be represented by a professional representative and act through him in all proceedings established by the EPC.

1.13 Notwithstanding the above, in the notice of opposition Rechtsanwalt Dr Andreas Mylaeus, who is qualified in accordance with Article 134 EPC to represent parties to proceedings before the EPO, was expressly appointed as common representative by all opponents named in the notice of opposition ("*Die Einsprechenden bestellen als gemeinsamen Vertreter Dr. Andreas Mylaeus. Die Vollmacht liegt bei, siehe Anlage Nr. 4*"). However, the notice of opposition itself had not been signed by Dr Mylaeus as the common representative. Since the opposition division's communications of 20 January 1997 and 14 August 1998 requesting the correction of certain deficiencies in the notice of opposition did not correctly reflect the factual and legal situation created in the present case by the above-mentioned acts of the parties and the opposition division itself (see 1.5 and 1.7 above), from a legal point of view those

communications and the time limits set in therein must be considered irrelevant.

1.14 Since Dr Mylaeus signed the notice of opposition as an opponent and since he subsequently declared in the letter of 27 February 1997 signed by him that he had been authorised to represent all those mentioned in the notice of opposition, the board considers he can be viewed as common representative as if he had signed the notice of opposition in that capacity in due time in accordance with Rule 36(3) EPC.

1.15 It follows from Rule 100(1) EPC that several persons acting in common in filing a notice of opposition are filing only one opposition and from Article 99(1), last sentence, EPC, that only one opposition fee must be paid in due time in order for the opposition to be deemed to have been filed - see G 3/99 (*loc. cit.*), especially Reasons, point 10.

1.16 In view of the foregoing observations, the board concludes that opposition I fulfils all the requirements of Article 99(1) and of Rule 55 EPC and is therefore admissible.

Admissibility of opposition II

1.17 Opposition II has been filed in common by two natural persons, Mr. Hüppe and Mr. Rösler but only signed by Mr. Hüppe. Both opponents are clearly identified in the notice of opposition by their name and address.

1.18 In the present case, Mr. Hubert Hüppe was the opponent first named in the notice of opposition and, therefore,

considered to be the common representative in filing the notice of opposition on behalf of them both (Article 133(4) EPC and Rule 100(1), second sentence, EPC), the additional signature of Mr. Rösler not being required.

1.19 It follows from Rule 100(1) EPC that several persons acting in common in filing a notice of opposition are filing only one opposition and from Article 99(1), last sentence, EPC, that only one opposition fee must be paid in due time in order for the opposition to be deemed to have been filed (see 1.15 above).

1.20 The withdrawal of the common opponent Mr. Rösler from opposition proceedings was duly announced to the EPO by the newly appointed common representative determined under Rule 100(1) EPC and took effect on 29 May 1999.

1.21 In view of the foregoing, no objections can be raised against the admissibility of opposition II.

Admissibility of opposition III

1.22 No objections have been and can be raised against the admissibility of opposition III.

2. *Admissibility of the Appeal*

2.1 As is apparent from XIV [26] - [28] above, the respondent provided reasoned arguments to contest the admissibility of the appeal.

2.2 The board concurs with the respondent's opinion that the applicability of Rule 65(2) EPC in conjunction with

Rule 64(a) EPC is to be defined as the requirement that deficiencies and omissions in information concerning the appellant are to be remedied on invitation in accordance with Rule 65(2) EPC, while the identity of the appellant must be known and verifiable from the outset of proceedings. If this is not so, any party to the proceedings adversely affected by a decision referred to in Article 107 EPC, as initiating the appeal proceedings will not exist (see T 25/85, OJ EPO 1986, 81, especially Reasons, point 11 and generally "Case Law of the Boards of Appeal of the EPO", 4th edition 2001, pages 525-526, VII.D.7.4)

2.3 However, the requirement regarding sufficient identification of the appellant is to be considered to be met whenever it is possible to establish beyond reasonable doubt the identity of the appellant on the basis of all information provided by the appellant or his legal representative within the two month time limit according to Article 108, first sentence, EPC or in the previous proceedings, including any such information contained in the decision under appeal.

Thus, for example, in decision T 483/90 of 14 October 1992 the board held that the appellants were sufficiently identified if, in the notice of appeal, their name was incorrectly given and their address was missing but the number of the contested patent and the name and address of the professional representative were the same as those cited in previous proceedings and the appellants were referred to as the opponents in those proceedings.

In T 867/91 of 12 October 1993 the notice of appeal designated the patent in suit by its number and the decision under appeal by its date. It also contained the name of the patentee, as well as the name and address of the appellant's representative. It did not contain the address of the appellant and did not expressly state that the patentee was the appellant. The board held that the requirements of Rule 64(a) EPC had been met since the notice of appeal provided sufficient information to identify the appellant and his address (both decisions cited in "Case Law", 4th edition 2001, page 526, VII.D.7.4)

- 2.4 In the present case, opponent I was represented in the proceedings before the opposition division by the common representative Dr Mylaeus who had filed the submissions of the common opponent I in these proceedings under reference "AM-97/931". Since the same Dr Mylaeus also filed the notice of appeal using the same reference, it was possible in conjunction with the additional information in the notice of appeal to establish beyond reasonable doubt the identity of the appellant as opponent I.
- 2.5 Since the appeal of the party who has appealed is from a decision in an opposition (opposition I) which is itself admissible (see 1.4 to 1.16 above), and since the appeal complies with Articles 106 to 108 and Rule 64 EPC, the admissibility of the appeal is not in question.

Main request

3. *Articles 84 and 123 EPC*
- 3.1 A formally adequate basis for the replacement of the references to "a mammal", "the mammal" or "the animal", wherever they existed in the description and the claims of the patent as granted (see claims 5, 8 and 13) and whatever their context, by references to "a lower mammal" or "the lower mammal" is found in the application as originally filed (International application No. PCT/US91/09637; International publication number WO 92/11009) at lines 4-5 on page 1 ("*The present invention relates to euthanasia compositions which are used for producing humane death in **lower mammals***") and at lines 10-12 on page 1 ("*euthanasia compositions for **lower mammals** are necessary in order to provide humane death*"). The requirements of Article 123(2) EPC are accordingly met.
- 3.2 Insertion of the additional feature "*lower*" before the word "mammal" in amended claims 5, 8 and 13 for all designated contracting states results in a limitation of the conferred protection (see II and V above). The requirements of Article 123(3) EPC are accordingly also met.
- 3.3 In the board's judgment, the expression "lower mammal" is sufficiently clear as to exclude human beings. Accordingly, claims 5, 8 and 13 as amended to contain a reference to a "lower mammal" are not on that ground objectionable under Article 84 EPC. Moreover, Article 102(3) EPC does not allow objections to be based upon Article 84 EPC, if they do not arise out of

the amendments made to the patent during an opposition. This is the case here since claim 14 as granted contained already a reference to "a lower mammal" (see "Case Law of the Boards of Appeal of the European Patent Office", fourth edition 2001, EPO 2002, VII.C.10.2, pages 488-489).

3.4 The appellant's argument that, in view of the amendments to the description, present claim 1 is now broader in scope than the description and therefore no longer supported as required by Article 84 EPC, is unfounded. The board considers it is clear that the product of claim 1 as such is to be found in the description (see 9.2 to 9.4 below).

4. *Patentability - Articles 52(1) and 54-57 EPC*

4.1 There is a clear and unequivocal statement in the introductory portion of the application as originally filed and published (International application No. PCT/US91/09637, published under the PCT as WO 92/11009) to the effect that the object of the present invention is to provide euthanasia compositions which are used in veterinary practice to produce humane death in lower animals. (*See "The present invention relates to euthanasia compositions which are used for producing humane death in lower animals. In particular, the present invention relates to euthanasia solutions which use the anesthetic gamma-hydroxybutramide (embutramide) as a basis for formulating the composition. Euthanasia compositions for lower mammals are necessary in order to provide humane death. Generally the solutions are injected intravenously or intraperitoneally. Users of such solutions are shelters,*

humane societies, veterinarians, veterinary hospitals, zoos and researchers. The owners of such animals are concerned with providing a humane death" - application as originally filed and published page 1, lines 3-16). The identical text is also found in the patent both in the form as granted and as maintained by the opposition division (see page 3, lines 7-16).

- 4.2 The compositions according to the present invention are disclosed in great detail in the patent description and are defined in claim 1 as follows:

"A composition which comprises an aqueous solution comprising,

- (a) a cardiotoxic compound selected from the group consisting of a quinacrine salt and a chloroquine salt in a cardiotoxic amount; and
- (b) embutramide in a lethally anesthetic amount."

- 4.3 In this connection, the board observes (with reference to citation (1)) that:

- the unequivocal, generally accepted and exclusive meaning, both in veterinary practice in general and in the field of veterinary medicine and pharmacology in particular, of the expression "euthanasia" is the humane killing or mercy killing of animals by trained personnel to prevent suffering from incurable or painful conditions (see citation (1), page 1143, left-hand column, lines 1-3) and that
- euthanasia compositions for mercy killing of lower animals are well known in veterinary practice;

such compositions are widely used and considered by many practitioners to be absolutely necessary and indispensable tools in veterinary medicine for providing humane death or mercy killing of animals so as to alleviate the animals' suffering (see citation (1), page 1144, left-hand column, line 12 from the bottom to page 1147, left-hand column, end of the first paragraph).

Citation (1) represents an excerpt from a standard text book in the field of veterinary medicine, pharmacology and therapeutics and its content reflects the common general knowledge and state of the art before the priority date of the patent. The above is in agreement with the disclosure on page 3, line 13 of the patent where is stated that "*euthanasia compositions for lower mammals are necessary in order to provide humane death*".

- 4.4 Article 52(1) EPC headed "Patentable inventions" states that European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step. Paragraph 1 of this article lays down the four requirements for the grant of an European patent: there must be an
- (i) an invention that is
 - (ii) new,
 - (iii) based on an inventive step and
 - (iv) capable of industrial application.

- 4.5 The EPC does not define the concept of the invention. Article 52(2) EPC is merely a negative list of what cannot be an invention according to the EPC.

Nevertheless important indications for the concept of the invention can be found in the EPC and the implementing regulations. According to Articles 54(1) and 56 EPC, it is the state of the art that forms the basis for the assessment of an invention. The technical character of an invention is emphasized in Rule 27(1) (a) and (c) EPC. In accordance with the case law, subject-matter is to be regarded as an invention if it has a technical character i.e. if it provides a technical contribution to the art (see "Case law of the Boards of Appeal of the European Patent Office", 4th Edition 2001, page 1).

4.6 The composition, comprising the chemical compounds (a) and (b) described in more detail in technical terms in the patent description and defined and claimed in terms of its technical features in claims 1 to 13, is according to the invention intended for use in veterinary medicine for euthanasia of lower animals or for preparing a medicament for such euthanasia (see claim 14). Such compositions represent thus technical tools or means provided and intended to achieve the indicated effect and to fulfil the specified purpose. The present invention has thus a clearly technical character and is thus an invention within the meaning of Article 52(1) EPC. This was not disputed by the appellant.

4.7 Article 54(1) EPC provides that "an invention shall be considered to be new if it does not form part of the state of the art". There is no dispute that a composition *per se*, as described in the patent specification and defined in claim 1, comprising the components (a) and (b) in any conceivable amounts or

proportions, is not disclosed in the state of the art available in the proceedings. It necessarily follows that the claimed subject-matter meets the requirement of novelty within the meaning of Article 52(1) in conjunction with Article 54(1) EPC. Since lack of novelty was not invoked as a ground for opposition, there is no need to give more detailed reasons in this decision. The conclusions above extend not only to the compositions according to claims 1 - 13 but also to their use claimed in claim 14.

4.8 There is a dispute, however, as to whether the claimed subject-matter involves an inventive step. Article 56 EPC, first sentence, provides that *"an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."* The appellant, in its notice of opposition, invoked Articles 100(a) and 56 EPC as a ground for opposition.

4.9 There was general agreement that citation (1) constitutes the closest state of the art. This citation discloses the euthanasia solution "T-61" (see page 1145) which is used in veterinary practice and comprises as an essential active component the gamma-hydroxybutramide compound embutramide. As also acknowledged and undisputed by the parties, in the introductory portion of the patent description this solution contains as solids 78% of the anesthetic gamma-hydroxybutramide (N-2-(methoxyphenyl)-2-ethylbutyl-1-hydroxybutyramide, embutramide), 2% of the local anesthetic tetracaine hydrochloride, i.e. (4-(Butylamino)benzoic acid 2-(dimethylamino)ethyl ester hydrochloride and 20% of the muscle relaxant mebezonium,

- i.e. (4,4'-Methylene bis(cyclohexyltrimethylammonium) diiodide and as liquids a mixture of 60% dimethylformamide ("DMF") and 40% water (see page 3, lines 21-25).
- 4.10 The patent specification refers to a number of unwanted and adverse side-effects associated with the use of "T-61" for the euthanasia or mercy killing of animals. As explained at lines 35-41 on page 3 of the patent description, it was found that the presence of tetracaine hydrochloride in the "T-61" euthanasia solution is responsible for bizarre behavioural effects e.g stiffening of the forelimbs, opisthotonos, and an uneasy appearance when tetracaine was given at the dose contained in "T-61".
- 4.11 It is further indicated in the patent description (see page 3, lines 49-52) that the major drawback resulting from the use of "T-61" as a euthanasia agent is the appearance of a noticeable heart beat which persists during the euthanasia procedure. It is also explained that this activity of the heart is visible, for example, in thin chested dogs or small animals and usually exists for many minutes and that this appearance is not aesthetically pleasing to the owner or to people performing this task who are not familiar with the time course of lethal effects or hypoxia.
- 4.12 A further disadvantage appears to be the high concentration of DMF in "T-61" solutions which is responsible for certain discomforts described in more detail at lines 42 to 48 on page 3 of the patent description. The appellant did not dispute that these

were disadvantages of the prior art in the form of "T-61" and the board sees no reason to doubt this.

- 4.13 The problem to be solved by the present invention is that of providing effective euthanasia formulations which are used for producing humane death in lower animals and which overcome the above-mentioned drawbacks in the closest prior art.
- 4.14 The proposed solution is the provision of the compositions comprising the components (a) and (b) which are precisely described in the patent specification and claimed in claim 1. Those compositions differ from the closest state of the art, i.e. the euthanasia solution "T-61", in that they are provided in the form of aqueous solutions containing as the active agents a quinacrine salt or a chloroquine salt as component (a) in combination with embutramide as component (b). "T-61" contains, in contrast to the compositions according to the invention, tetracaine hydrochloride and mebezonium in combination with embutramide as the active agents.
- 4.15 On the basis of the compendious experimental results presented in the patent (see the examples and, in particular, example 12) and in the complete absence of any evidence to the contrary, the board is satisfied that the problem has been plausibly solved over the whole extent claimed. In interpreting the instruction in claim 1 to use in the claimed compositions (a) the cardiotoxic compound selected from the group consisting of a quinacrine salt and a chloroquine salt in a cardiotoxic amount and (b) embutramide in a lethally anesthetic amount a skilled person will, even on the

basis of his general knowledge and his familiarity with the state of the art, rule out unrealistically small or large amounts. He will also be guided by the preferred ranges of the amounts and ratios of components (a) and (b) mentioned at lines 47-57 on page 4 of the patent description and in claims 5, 7, 8 and 13, which are indicated in relation to the body weight of the lower mammal, in seeking other suitable ratios and amounts of the components (a) and (b). Moreover, the skilled person is given precise directions - should he really need them - as to how he can by means of various tests determine the required amounts and ratios of both components (a) and (b) to achieve the optimum effect and results. The effort called for on the part of a skilled person must be regarded as reasonable, since such tests are quite normal in the art and those used in the present case are no more elaborate than usual. The problem is therefore solved in its entirety by the claimed invention.

4.16 The question still remains whether or not an inventive step was necessary to arrive at the present invention when starting from the basis of the euthanasia solution "T-61" known from the nearest prior art according to (1). Citation (1) itself does not contain any teaching or suggestion or hint pointing those skilled in the art in the direction of the proposed solution of the actual problem.

4.17 The lethal cardiotoxic effects on the heart of toxic doses of chloroquine and quinacrine, which are antimalarial drugs in human beings, have been recognized in the state of the art and are described, for example, in (2) - see especially page 342, right-

hand column, paragraph 2 and Table 14-8 - and in (3) - see especially page 834, Experiment 3, Table II and Graph II; page 834, Experiment 4, Table III and Graph III. However, there is not the slightest suggestion either in citation (2) or in citation (3) which could be regarded by a skilled person as an incentive to solve the problem stated above either by using cardiotoxic amounts of chloroquine salts or quinacrine salts as the sole active agents or by substituting a quinacrine salt or a chloroquine salt for tetracaine hydrochloride and mebezonium used in (1) as the active agents in combination with embutramide. On the contrary, citation (1) (see especially page 1148, left column, paragraph 2) advises against using cardiac drugs, such as myocardial depressants, for euthanasia in veterinary practice.

- 4.18 Moreover, the declarations (4) by Dr Taylor show clearly that high doses of chloroquine approaching the lethal dose of chloroquine alone would not be suitable for euthanasia in lower animals; the unacceptable side-effects demonstrated in these declarations would preclude its use at these doses for producing humane death in lower animals.

There was nothing in the cited documents, taken either in isolation or in combination, to suggest to a skilled person that adverse effects associated with the use of quinacrine salts or chloroquine salts alone could be avoided and that the problem underlying the present invention could properly be solved by combining embutramide with such salts.

4.19 In its written submissions and at the hearing before the board, the appellant relied heavily upon decisions T 69/83 (*loc. cit.*, especially Reasons, point 7) and T 296/87 (*loc. cit.*, especially Reasons, point 8.4) in support of its argument that the proposed solution to the problem posed was obvious to the man skilled in the art from a combination of the teaching of citation (1) with that of citations (2) and (3).

From the foregoing observations it is clear that the present case is not comparable with those decided in those decisions. As explained above, the use of quinacrine salts or chloroquine salts was in the circumstances of the present case certainly not the only realistic possibility, and definitely not an obvious possibility, to solve the problem posed. The state of the art did certainly not oblige the skilled person to adopt the proposed solution in the patent in the sense of the situation underlying the above-mentioned decisions. On the contrary, as shown above, the state of the art provided no incentive, not even the slightest suggestion, to the skilled person to substitute a quinacrine salt or a chloroquine salt for tetracaine hydrochloride and mebezonium used in (1) as the active agents in combination with embutramide in order to solve the problem posed. On the contrary, the experimental results reported in the declarations (4) by Dr Taylor offered no promising suggestion or lead in the direction of the proposed solution.

4.20 In view of the foregoing observations, the claimed subject-matter is based on an inventive step within the meaning of Article 56 EPC.

4.21 The euthanasia compositions according to the invention are chemical compositions which are exactly described in the patent description and defined in the claims and which have definite chemical and physical properties. Such compositions can be manufactured for the particular intended use in industry. The present invention is thus also susceptible of industrial application within the meaning of Article 57 EPC.

5. *Article 53(a) EPC - morality and "ordre public"; introductory remarks and interpretation*

5.1 Having established above that the present invention meets all basic substantive requirements for a European patent which are laid down in Article 52(1) EPC in conjunction with Articles 54, 56 and 57 EPC, the question arises whether or not the exclusion in Article 53(a) EPC would be a bar to patenting the present invention. All the opponents invoked in their notices of opposition Article 100(a) in conjunction with Article 53(a) EPC as a ground for opposition.

5.2 This Article provides that *"European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States."* This exclusion applies even if an invention otherwise meets all basic substantive requirements for the European patent laid down in Article 52(1) EPC. Article 53(a) EPC is thus an exception to the general entitlement to a patent in Article 52(1) EPC and is to be construed narrowly,

given the EPC's underlying objective of establishing a comprehensive patent protection between the contracting states (see Preamble of the EPC, paragraph 2).

5.3 The appellant asserted that, having regard to the case law of the boards of appeal, such a restrictive interpretation of Article 53(a) EPC is not what is intended by the Convention (see XIII [03] - [10] above). The board of appeal case law cited by the appellant in support of that assertion does not, in the board's judgment, assist the appellant's case.

5.4 The board cannot share the appellant's view and considers that it appears to be generally accepted that Article 53(a) EPC is to be construed narrowly and that such a restrictive interpretation is, while having regard to the particular circumstances of each individual case, not only correct but also justified (see, for example, Decision of the opposition division of the EPA "Relaxin" of 8 December 1994, OJ EPO 1995, 388, especially Reasons, point 6.2.2; Benkard/Mellulis, Artikel 53, Rdnr. 7, 8; Benkard/Bruchhausen § 2 PatG, Rdnr. 2; Singer/Lunzer, Rdnr. 53.01; Singer/Stauder/Schatz, Art. 53, Rdnr. 4; J. Busche, GRUR Int. 1999, 301). Decision T 356/93 (OJ EPO 1995, 545) is particularly relevant and illustrative in this respect:

"From the historical documentation relating to the EPC it appears that the view according to which "the concept of patentability in the European patent law must be as wide as possible" predominated (see document IV/2071/61-E, page 5, point 2, first paragraph). Accordingly, the exceptions to patentability have been

narrowly construed, in particular in respect of plant and animal varieties (see, for example, T 320/87 and T 19/90). In the board's view, this approach applies equally in respect of the provisions of Article 53(a) EPC" (emphasis added, see especially Reasons, point 8).

5.5 It is, in the board's opinion, only possible to read the words "contrary to "ordre public" or morality" in Article 53(a) EPC as qualifying the objective facts, namely "*publication or exploitation*" of the invention. Thus, the criteria of "ordre public" and morality are to be applied to determine whether the publication or exploitation of the invention infringes these fundamental principles. The board makes the following three observations in this respect.

5.6 First, the exclusion under Article 53(a) EPC is only applicable if either or both of the objective facts ("*Tatbestände*) *publication and/or exploitation* of the *invention* would contribute causally to the infringement of the fundamental principles of "ordre public" and morality. Accordingly, Article 53(a) EPC raises in the present case, for example, no question of

- (a) whether or not the invention *per se*, i.e. the claimed composition *per se*, or their preparation might be regarded as breach of the principles of "ordre public" or morality (see T 315/03, OJ EPO 2006, 15, especially Reasons, point 4.2; J. Busche, GRUR Int. 1999, 301, right hand column, lines 5-11; Benkard/Melullis, Artikel 53, Rdnr. 6; MGK/Moufang, Rdnr. 43);

- (b) whether and under what conditions the act of granting the patent either for the claimed compositions *per se* or for their preparation or for their use might be regarded as an infringement of ethical principles and contrary to "ordre public" within the meaning of Article 53(a) EPC (see e.g. T 315/03 (*loc.cit.*), especially Reasons, point 4.2; Busche, GRUR Int. 1999, 301; Singer/Stauder/Schatz, Art. 53, Rdnr. 8);
- (c) whether or not the making of the present invention as such or the inventor's activities during making or development of his invention or the development of the present invention as such might be regarded as breach of the principles of "ordre public" or morality (see eg T 315/03, (*loc.cit.*), especially Reasons, point 4.2; Benkard/ Melullis, Artikel 53, Rdnr. 6; MGK/Moufang Art 53 Rdnr. 43).

5.7 Second, *exploitation* of the *invention* within the meaning of Article 53(a) EPC is to be construed as the normal avowed use indicated in the patent ("bestimmungsgemäßer Gebrauch) of the invention's teaching (see e.g. G 1/98, OJ EPO 2000, 111, especially Reasons, point 3.3.3 - see XIV [35] above; Benkard/Melullis, Artikel 53, Rdnr. 6 and 8; Singer/Stauder/Schatz, Art. 53, Rdnr. 9; MGK/Moufang Art 53, Rdnr. 43, 47). In this respect, specific reference is made to the identically worded decisions G 1/03, (OJ EPO 2004, 413) and G 2/03 (OJ EPO 2004, 448), especially Reasons, point 2.4.1:

"The provisions on patentable inventions contain several exceptions to patentability. Examples are

methods for medical treatment under Article 52(4) EPC and inventions the exploitation of which is contrary to "ordre public" or morality under Article 53(a) EPC. In such cases, it may happen that a general claim comprises embodiments which fall under the exception, whereas the rest is patentable <..... >. Suppose the application contains a broad teaching applicable to mammals in general and mentions cattle as specific embodiments and the claims are directed to the treatment of mammals, a disclaimer necessary to exclude human beings in order to satisfy Article 53(a) EPC could not be based on the original text of the application which would only cover a broader limitation to cattle. The disclaimer "non-human" in respect of living beings has, however, nothing to do with the technical teaching in the application, it merely excludes beings to which this teaching, although theoretically workable, should never have been applied anyway. Similar situations arise in applications directed to the killing of animals".

- 5.8 Third, patent protection is only to be denied pursuant to Article 53(a) EPC if the intended exploitation, i.e. the avowed use indicated in the patent, ("bestimmungsgemäßer Gebrauch") of the invention would infringe "ordre public" or morality. It is not sufficient that the invention can **also** be exploited in this way; for example, if the intended exploitation of the invention does not infringe the principles of "ordre public" and morality it is not sufficient that one out of several or more or even all other conceivable exploitations or uses of the invention's teaching would be or could be regarded as breach of the principles of "ordre public" or morality, even if that

exploitation constituted a serious breach of the principles of "ordre public", for example a criminal offence. The mere possibility of abuse of the invention is not sufficient to deny patent protection pursuant to Article 53(a) EPC, if the invention can also be exploited in a way which does not and would not infringe "ordre public" and morality. (Benkard/Mellulis, Artikel 53, Rdnr. 7-9; Singer/Stauder/Schatz, Art. 53, Rdnr. 9; Benkard/Bruchhausen § 2 PatG, Rdnr. 4; MGK/Moufang, Artikel 53, Rdnr. 43, 47).

- 5.9 Furthermore, the board notes that, with respect to a possible breach of morality or "ordre public", the wording of Article 53(a) EPC explicitly refers to the invention and **not** to the scope of protection conferred by the claims.
6. *Article 53(a) - morality and "ordre public" and the present invention*
- 6.1 The Article 53(a) EPC objections require an assessment as to whether or not exploitation or publication of the present invention would be contrary to morality or "ordre public" on the basis of the principles laid down in 5.6 to 5.8 above. In the course of the present proceedings, objections based on the concepts of morality and "ordre public" were numerous, varied and often contradictory.
- 6.2 Before making that assessment, it appears necessary and useful to deal with the principal arguments advanced by the parties in the appeal proceedings in relation to Article 53(a) EPC. A large number of the arguments of the parties made in relation to Article 53(a) EPC were

- directed to issues with which the present case is quite simply not concerned.
- 6.3 The parties opposed to the patent argued that the object of the present invention was the provision of a composition for killing or for termination of life of all kind of living beings, including all animals and human beings. From this they concluded that the exploitation or avowed use indicated in the patent of the present invention included the arbitrary or intended termination of life (killing) or termination of life on demand (euthanasia) of all kinds of animals, including human beings (see XIII, [10] - [12] above). The above conclusion is based on a clear misinterpretation of the EPC and the teaching of the patent and is incorrect.
- 6.4 In this context, it appears necessary to note that only the content of the patent determines the extent of disclosure and information regarding the present invention. The avowed use or exploitation of the euthanasia compositions disclosed in the patent for any other conceivable purpose than for the sole intended purpose indicated in the patent in accordance with the present invention. i.e for producing humane death (mercy killing) in lower animals, has neither been indicated nor contemplated nor foreshadowed at all in the present patent.
- 6.5 The board cannot share the appellant's view that the text of the patent and, in particular, the paragraph "Objects" on page 4 of the patent description could be read as ambiguous as to the avowed use or exploitation of the euthanasia compositions disclosed in the patent.

It is clearly said in the cited passage on page 4 that *"it is the object of the present invention to provide improved euthanasia compositions which rapidly eliminate the presence of noticeable heart beat and the stiffening encountered with "T-61"*. Since it has been made abundantly clear in the patent description, and is known from the state of the art, that the designation "T-61" relates to euthanasia solutions for producing humane death in lower animals, it is also abundantly clear that the above cited reference in the patent must relate to euthanasia compositions which are provided in accordance with the present invention for the sole purpose of producing humane death in lower animals.

6.6 Contrary to the appellant's assertions in its written submissions, the board is unable to recognize that the patent contains at lines 57-59 on page 4 a reference to the toxicity of chloroquine in humans. The passage cited by the appellant explicitly refers to preferred amounts of the cardiotoxic compound which are used in accordance with the present invention per kg of body weight of the lower mammal.

6.7 The term "euthanasia compositions" used in the patent is so clearly defined and limited throughout the patent to compositions which are used for the sole purpose of producing humane death in lower animals (see citation (1)) that *bona fide* a different interpretation - such as the alleged additional use of the compositions for the termination of human life - is entirely excluded and in no way derivable from the patent description.

6.8 In view of the foregoing observations the following arguments of the parties need not be considered further:

(a) The argument that the patent is open to objection under Article 53(a) EPC because the intended exploitation or publication of the present invention indicated in the patent relates to or at least includes the arbitrary or intended killing or euthanasia of all kinds of living beings other than lower animals, for example human beings (see XIII, [10] - [12] above). The intended exploitation and publication of the present invention (the avowed use of the invention's teaching indicated in the patent) is strictly limited to the use of the claimed composition for providing humane death in lower animals and the disclosure in the patent excludes the exploitation of the present invention for the arbitrary or intended termination of life, on demand or otherwise, of all kinds of living beings, including humans.

(b) The argument the patent contravenes Article 53(a) EPC because the animal experiments reported in the patent are contrary to morality and "ordre public" (see XIII [14] above). These experiments were carried out during the making or development of the invention and as such do not fulfil the condition of being part of the exploitation of the present invention (see 5.1 and 5.6(c) above).

(c) The argument that the patent is open to objection under Article 53(a) EPC because the claimed compositions *per se* and the grant of a patent for the compositions according to claims 1 to 13 represent an infringement, or at least an abstract risk of

infringement, of certain basic principles of "ordre public", in particular of the rights as guaranteed by Article 2 ECHR (see XIII [16] - [17] above. Neither the invention *per se* nor the act or conditions of patenting the claimed invention fulfil the condition of being part of the exploitation of the present invention (see 5.1 and 5.6(a) to 5.6(c) above).

- 6.9 When now making an assessment of whether or not the publication or exploitation of the present invention would be contrary to "ordre public" or morality, an attempt can be made to refer to certain general principles of "ordre public" and morality. As is apparent from the wording of Article 53(a) EPC itself, "ordre public" and morality may form the basis of two separate objections either or both of which can be raised in a particular case (and are both raised in the present case). As regards "ordre public", the reference below provides this summary:

Thus, in general "Ordre public" is formed by the ethically based constitutional or other rules, usually backed up by penal provisions, that reflect the basic values prevailing in society and trade. These protected values can in particular include public safety, the integrity of the individual and nowadays, certainly also the protection of environment" (see Singer/Stauder/Schatz, Art. 53, Rdnr. 11).

- 6.10 There is clear evidence on file that the unequivocal, generally accepted and exclusive meaning and scope in the field of veterinary medicine and practice for the expression "euthanasia" is the humane killing or mercy killing of animals by trained personnel. Euthanasia is

a professional term used in preference to more widely understood lay terms such as killing, mercy killing, or humane killing. In veterinary practice animals are generally euthanised to prevent their suffering from incurable or painful conditions (see (1), page 1143, left-hand column, lines 1-5). Document (1) makes it clear beyond doubt that the killing of animals for any other reasons than those mentioned above does **not** fall within the meaning and scope of the term "euthanasia". It is further explained in (1) that no veterinarian enjoys killing animals and that euthanasia is one of the saddest and most disagreeable aspects of veterinary practice. Nevertheless, veterinarians euthanise animals to alleviate their suffering. The veterinarian is not obliged to kill animals that are not suffering and may refuse to do so if the animals could be placed with other people (see (1), page 1143, right-hand column, first full paragraph).

- 6.11 If the guidance in 6.9 above is applied to the present case, it should first be mentioned that absolutely no evidence has been provided by the appellant or the other parties in the course of the entire proceedings that euthanasia of lower animals under the particular conditions described in 6.10 above - and the board has no reason to doubt that the euthanasia compositions defined in claim 1 are provided for use by trained personnel observing these conditions - would obviate any ethically based constitutional or other rules. Thus, there is no evidence available that the exploitation of the present invention within the limits explained in 6.10 above would breach or even jeopardize public peace or social order or seriously prejudice the environment. On the contrary, from citation (1) it is clear that

veterinarians are generally authorized to euthanise animals to alleviate their suffering. Accordingly the board considers that the intended exploitation and publication of the present invention is not contrary to "ordre public" within the meaning of Article 53(a) EPC.

- 6.12 Turning from "ordre public" to morality, it should be noted as a preliminary point that morality is not a criterion to be determined by the patent authorities. No single definition of morality based on e.g. socio-ethic, economic or religious principles represents an accepted standard in European culture. Nevertheless, when now making the necessary assessment of whether or not the publication or exploitation of the present invention would be contrary to morality, an attempt can be made to refer to certain general principles of morality:

Morality is an old legal concept. It was adopted in western legal systems from Roman law as "boni mores". Morality is one of the fundamentals of our legal system and at the same time forms the basis for the inclusion of extra-legal principles of ethics in the law. The legal approach based on morality for the EPC can be found in the concepts of the European cultural and legal systems. Morality constitutes actual ethically-based norms of behaviour that have become socially binding through being generally accepted. The exploitation of an invention only infringes morality if it is regarded as reprehensible by society in general or at least by the trade concerned. (see Singer/Stauder/Schatz, Art. 53, Rdnr. 16-18); and see also T 356/93, (loc.cit.), point 6 of the Reasons).

6.13 To find an answer to the question whether or not the publication or exploitation of the present invention is contrary to morality, the board considers it useful to start again from what is meant by euthanasia in veterinary practice and medicine, namely the humane killing or mercy killing of animals suffering from incurable or painful conditions by trained personnel for the sole purpose of preventing prolonged suffering of the animals (see (1)). As is explained in (1), no veterinarian enjoys euthanasing animals and veterinarians consider it nevertheless as their moral obligation based on generally accepted ethics and norms which the board accepts are deeply rooted in the culture inherent in European society and civilisation. Moreover, it is also made clear in (1) that no veterinarian is obliged to kill animals that are not suffering and may refuse to do so if the animals could be placed with other people. Many veterinarians can offer some sort of unofficial placement service for the occasional unwanted animal (see (1), especially page 1143, right-hand column, first full paragraph).

6.14 On the basis of the above observations and in the absence of a convincing argument or evidence to the contrary, the board considers that the intended exploitation and publication of the present invention is not contrary to morality within the meaning of Article 53(a) EPC.

6.15 The appellant also argued that the patent had to be revoked in any case because, as a result of the opposition division's finding that the patent as granted contained subject-matter in conflict with the principles of morality and "public order", the

publication of the patent application, on which the patent as granted was based, was itself contrary to Article 53(a) EPC (see XIII [13] above). The board notes that the request which gave rise to that finding of the opposition division is no longer in issue.

Further, the argument appears to the board to be misconceived: if it were correct, then there would in many cases be a risk (albeit in many cases very small) that the publication of a patent application could, as the result of a subsequent finding contrary to Article 53(a) EPC, be seen retrospectively as the offending publication within the meaning of that Article. It requires only a moment's thought to appreciate that this cannot have been the intention of the legislature: without publication there can be no objections, including Article 53(a) EPC objections, by any third party or opponent. It is manifestly absurd to suggest that the routine act of publication could retrospectively become the reason for refusing a patent application or revoking a granted patent.

Although relating to a somewhat different situation, namely the publication by oversight on the part of the EPO of subject-matter contrary to Article 53(a) EPC, the board agrees with the view expressed in MGK/Moufang, Art. 53, Rdnr. 42 that in such cases the protective purpose of Article 53(a) EPC would not justify the later revocation of the granted patent on the grounds that the publication had created the alleged infringement of morality or "ordre public". If correct for the exceptional case of a mistaken publication, this reasoning must hold true for cases, such as the present, in which publication takes place

in the normal course of the application procedure and before any objection under Article 53(a) EPC has been made.

6.16 In view of the foregoing it becomes clear that the present invention cannot be refused under Article 53(a) EPC.

7. Since the main request is allowable, there is no need to examine the auxiliary requests.

8. The conclusions above extend not only to the claims for all designated contracting states except ES and GR but *mutatis mutandis* also for the separate sets of claims for the contracting states ES and GR.

9. *Further arguments raised by the appellant/opponents*

9.1 Both the appellant and the other opposing parties strongly objected to the acceptability of the product claims 1 to 13.

9.2 Article 84 EPC provides that the claims "shall define the matter for which protection is sought". Rule 29(1) EPC further requires that the claims "shall define the matter for which protection is sought in terms of the technical features of the invention". The primary aim of the wording used in a claim must therefore be to satisfy such requirements, having regard to the particular nature of the subject invention, and having regard also to the purpose of such claims. The purpose of claims under the EPC is to enable the protection conferred by the patent to be determined (Article 69 EPC), and thus the rights of the patent owner within

the designated contracting states (Article 64 EPC), having regard to the patentability requirements of Articles 52 to 57 EPC. It follows that the technical features of the invention are the physical features which are essential to it.

There are basically two different types of claim, namely a claim to a physical entity (e.g. product, composition, apparatus) and a claim to a physical activity (e.g. method, process, use). These two basic types of claim are sometimes referred to as the two possible "categories" of claim. When considering the two basic types of claim the technical features of a claim to a physical entity are the physical parameters of the entity, and the technical features of a claim to an activity are the physical steps which define such activity. A number of decisions of the boards of appeal have held that in appropriate cases technical features may be defined functionally (see e.g. T 68/85, OJ EPO, 1987, 228; T 139/85 EPOR 1987, 229). The latter is the case in present claim 1.

- 9.3 It is generally accepted as a principle underlying the EPC that, with the exception of a purpose-limited product claim under Article 54(5) EPC (which confers product protection upon that product limited to its use in a method referred to in Article 52(4) EPC), the EPC does not provide for any other type of purpose-limited product claims which would confer product protection upon a product limited to a specific use.

It follows - and is generally accepted as a principle underlying the EPC - that in cases such as the present where the invention consists in the provision of a

physical entity *per se*, such as, for example, a chemical compound or composition for a specified use or purpose, and that invention fulfils the patentability requirements of Articles 52 to 57 EPC, the applicant or patentee is entitled under the terms of Article 84 and Rule 29(1) EPC to seek absolute substance protection for said chemical compound or composition *per se*. The discovered use or purpose of such compound or composition must normally be described in the patent description, but may not be expressly claimed (see G 2/88 OJ EPO 1990, 93, especially Reasons, point 5).

9.4 It is, moreover, generally accepted as a principle underlying the EPC that a patent which claims a physical entity *per se*, for example a chemical compound or composition, confers absolute protection upon such physical entity; that is, wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown) - see G 2/88, *loc. cit.*, especially Reasons, point 5.

9.5 The conclusions above apply in all respects to the present composition claims 1 to 13. In the present case it has been established that the claimed composition *per se* meets the requirements for patentability laid down in Articles 52 to 57 EPC and the respondent (patentee) is therefore entitled under the terms of Article 84 EPC, first sentence and Rule 29(1) EPC to seek absolute substance protection for that particular composition in accordance with present claim 1 and dependent claims 2 to 13. As has already been clarified above in respect of Article 53(a) EPC, patent protection is only to be denied if the intended exploitation (the avowed use indicated in the patent)

of the invention would infringe "ordre public" or morality and this is not the case here. Accordingly, in the circumstances of the present case, Article 53(a) EPC provides no legal basis for denying absolute substance protection for the claimed composition *per se* on the grounds that, with the exception of the intended use or exploitation, one or more of several or even all conceivable other exploitations or uses of the claimed composition (falling within the scope of protection) would be or could be regarded as breach of the principles of "ordre public" or morality, even if such conceivable exploitation might constitute a serious breach of the principle of "ordre public", such as a criminal offence including the killing of humans (see Benkard/Mellulis, Artikel 53, Rdnr. 9).

- 9.6 There appears to be unanimity of doctrine that under Article 53(a) EPC patent protection for an invention which meets the patentability requirements laid down in Article 52(1) EPC must be granted if at least one exploitation or use of the patent's teaching does not infringe "ordre public" or morality and conversely patent protection can only be denied if virtually any exploitation or use which might be reasonably considered would infringe "ordre public" or morality (see Benkard/Mellulis, Artikel 53, Rdnr. 9, 10, J. Busche, GRUR Int. 1999, 301; Singer/Stauder/Schatz, Art. 53, Rdnr. 9; MGK/Moufang, Art. 53, Rdnr. 43, 47, with the numerous further references therein). On the basis of the observations in the foregoing points, the board would express the above principle more precisely, namely that under Article 53(a) EPC patent protection for an invention which meets the patentability requirements laid down in Article 52(1) EPC must be

granted if the intended exploitation or the avowed use of the invention indicated in the patent does not infringe "ordre public" or morality.

9.7 The patenting of an invention does not grant the patent holder a positive right to exploit the invention but rather the right to exclude others from exploitation during a limited period of time. Conversely, the refusal of patent protection does not mean that the exploitation of the invention is forbidden. Accordingly, patent law is generally not a legal instrument for averting or preventing abuses or risks associated with the exploitation of an invention, irrespective of whether a particular invention enjoys patent protection or not. Article 53(a) EPC is merely intended to prevent an invention, the publication or exploitation of which would infringe the fundamental principles of "ordre public" or morality being given an appearance of approval through a patent issued by an international authority.

9.8 It appears also useful to repeat that the mere possibility of abuse of the invention is not sufficient to deny pursuant to Article 53(a) EPC absolute patent protection, if the invention can also be exploited in a way which does not infringe "ordre public" and morality. Thus, for example, Article 53(a) EPC does not apply in general to the following type of inventions:

- abortifacients (in view of their possible exploitation for medical and therapeutical applications);
- poisons (in view of their possible exploitation as pesticides or insecticides);

- explosives (in view of their possible exploitation in mining);
- house-breaking tools (in view of their possible exploitation by a locksmith in emergency).

(Benkard/Mellulis, Artikel 53, Rdnr. 7-9;
Singer/Stauder/Schatz, Art. 53, Rdnr. 9;
Benkard/Bruchhausen § 2 PatG, Rdnr. 4; MGK/Moufang,
Artikel 53, Rdnr. 43, 47 and the references cited
therein).

9.9 For the sake of completeness, the board considers it important and useful to note that the scope of protection of the composition claimed in claim 1 would not be different or altered if the intended exploitation or the avowed use indicated in the patent for that composition was expressly mentioned in the claim (wrongly designated by the appellant as a "disclaimer"), as variously proposed by the parties. With the exception of cases falling under the terms of Article 54(5) EPC (see 9.3 above), a claim directed to a product *per se* (see present claim 1) confers absolute product protection upon that product which cannot be limited to a particular use or purpose of that product merely by specifying such a use or purpose in the claim. As already explained above, the legal construct of a purpose-limited product claim does not exist under the EPC, with the exception of cases falling under Article 54(5) EPC.

9.10 It is thus clear that the present product claim 1 and dependent claims 2 to 13 are neither objectionable under Article 84 and Rule 29(1) EPC nor under Article 53(a) EPC. As regards the appellant's objection that claim 1 is too broad, the board reiterates that

the breadth of a claim must not be confused with its scope of protection. Thus, for example, a claim directed to a single chemical component confers broad absolute protection upon such single compound; that is, wherever it exists and whatever its context (and therefore for all uses of such physical entity, whether known or unknown).

9.11 Use claim 14 is drafted in the so-called "second or further medical use format", although the particular intended application of the medicament "for providing euthanasia in a lower mammal" cannot, in the board's opinion, be considered a therapeutic method within the meaning of Article 52(4) EPC. However, the respondent is free to use this format for a claim seeking protection for the particular use of the composition according to claims 1 to 13 EPC.

9.12 Accordingly, these further arguments can make no difference to the board's decision.

10. *Request for removal of the letter of the Deutsche Gesellschaft für Humanes Sterben (DGHS) dated 21 January 1997 from the file or, as auxiliary request, its exclusion from public inspection*

10.1 The board concurs with the appellant that neither the content of the above-mentioned letter nor its annexes can be considered as constituting observations by third parties under Article 115 EPC but rather as an attempt to promote and support the alleged interests of parts of society in the legal admissibility of human euthanasia. In its letter of 29 April 1998, the opposition division informed the DHGS that the well-

understood purpose of this Article is to enable the public to present to the EPO in an informal way its adverse observations concerning the patentability of inventions the subject of European patent applications/patents. The observations by a third party are regularly taken into consideration by the department which is responsible to decide on the grant, maintenance or revocation a patent, if such observations provide legal or technical information relevant to the decision to be taken by that department. Since in the present case the submissions filed by DGHS contain no information which would be considered relevant to the present decision, they do not fall within the category of observations by a third party within the meaning of Article 115 EPC.

10.2 As far as the appellant's above-mentioned request is concerned, according to the decision of the President of the EPO dated 7 September 2001, which entered into force on 3 December 2001, concerning documents excluded from file inspection under Article 128(4) and Rule 93(d) EPC (see OJ EPO 2001, 459), documents or parts thereof

- (a) *shall be excluded from file inspection at the reasoned request of a party or his representative if their inspection would be prejudicial to the legitimate personal or economic interests of natural or legal persons;*
- (b) *may, exceptionally, be excluded from file inspection by the Office of its own motion if their inspection would be prima facie prejudicial to the legitimate personal or economic interests of natural or legal persons other than a party or his representative.*

This decision reflects Article 6 ECHR which guarantees the right to a fair trial.

- 10.3 Although the observations submitted by DGHS certainly express a different view from that of the appellant about certain aspects associated with the problem of human euthanasia, the board cannot recognise that these submissions would be prejudicial to the legitimate personal or economic interests of either the appellant or its representative or of any persons other than those mentioned before. The board sees therefore no reason which would allow the appellant's request.

Order

For these reasons it is decided that:

1. The appeal is dismissed.
2. The appellant's request concerning the documents submitted by the Deutsche Gesellschaft für Humanes Sterben is refused.

The Registrar:

The Chairman:

A. Townend

U. Oswald