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Bezeichnung der Erfindung: Pesticidal compositions

Title of invention:

Titre de l'invention :

Klassifikation / Classification / Classement : A 01 N 25/02

### ENTSCHEIDUNG / DECISION

vom / of / du 14 October 1987

Anmelder / Applicant / Demandeur : THE WELLCOME FOUNDATION LIMITED

Patentinhaber / Proprietor of the patent /

Titulaire du brevet :

Einsprechender / Opponent / Opposant :

Stichwort / Headword / Référence : Pigs I - Wellcome

EPÜ / EPC / CBE Art. 52(4), 57

Kennwort / Keyword / Mot clé : Therapeutical treatment includes treatment of ectoparasites on pigs - exclusion from patentability

#### Leitsatz / Headnote / Sommaire

- I. Under the proper interpretation of Articles 52 and 57 EPC in their context, even though the therapeutic treatment of animals is commonly an aspect of agriculture, and agricultural methods in general are potentially patentable subject-matter, nevertheless the particular methods of treatment of animals defined in Article 52(4) EPC are excluded from patentability. For the particular methods of treatment of animals defined in Article 52(4) EPC, the prohibition against patentability set out in Article 52(4) EPC takes precedence over Article 57 EPC.
- II. If a claimed method requires the treatment of an animal body by therapy, it is a method which falls within the prohibition on patentability set out in Article 52(4) EPC. It is not possible as a matter of law to draw a distinction between such a method

as carried out by a farmer and the same method as carried out by a veterinarian, and to say that the method when carried out by a farmer is an industrial activity and therefore patentable under Article 57, and when carried out by a veterinarian is a therapeutic treatment not patentable under Article 52(4). Nor is it possible as a matter of law to distinguish between the use of such a method for the treatment of ectoparasites and endoparasites.

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Case Number : T 116/85

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.1  
of 14 October 1987

**Appellant :** THE WELLCOME FOUNDATION LIMITED  
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**Decision under appeal :** Decision of Examining Division 001  
of the European Patent Office  
dated 29.11.1984 refusing European  
patent application No. 81 108 424.3  
pursuant to Article 97(1) EPC

**Composition of the Board :**

**Chairman :** K. Jahn

**Members :** J. Arbouw

G. D. Paterson

## Summary of Facts and Submissions

I. European patent application 81 108 424.3 filed on 16 October 1981 and published on 28 April 1982 with publication number 0 050 335, claiming priority of the South African application 806408 from 17 October 1980, was refused by a Decision of the Examining Division dated 29 November 1984. The Decision was based on Claim 1, filed on 6 September 1983, and Claims 2-12 as originally filed of which the only independent Claim 1 reads as follows:

"1. A method for the control of ectoparasitic infestations of pigs comprising the application to a localised area of the pig's body surface of a pesticidal composition comprising a pesticide admixed with an aliphatic hydrocarbon oil to substantially prevent systemic action of the pesticide.

II. The reason given for the refusal of the application by the Examining Division was that the subject-matter of the claims relates to a method for treatment of the animal body by therapy, which according to Article 52(4) EPC is not regarded as an invention which is susceptible for industrial application and is therefore not patentable (Article 52(1) EPC). The reasoning in the Decision draws a distinction between "temporary" and "permanent" ectoparasites, the latter staying for at least part of their life cycle on their host, and thus infecting the host animal. It is stated that in the experimental part of the description in the patent application, only pigs infested with mange mites are treated, and that the invention is therefore primarily concerned with the treatment of permanent ectoparasites. A mite infestation on animals is called "mange", which is considered as a disease. Several species of such ectoparasites cause direct harm to the infested host: the control or eradication of permanently

dwelling ectoparasites was therefore considered to be a therapeutic treatment of the animal body.

III. The Appellant filed an appeal on 28 January 1985 against the above decision, paying the prescribed fee at the same time. A statement of grounds of appeal was filed on 28 March 1985.

The submissions of the Appellant in the grounds of appeal are essentially as follows:

- (1) The treatment of ectoparasites is not a medical treatment. A distinction should be drawn between the individual treatment of animals, for example by a veterinarian, and treatment activities which are normally routinely carried out by a farmer. Farming should be considered not as a veterinary treatment but as capable of industrial application.
- (2) The locus of an ectoparasite is unimportant. The active ingredient is a pesticide which could equally be applied to the animals or to the interior of a pig house.
- (3) Mange is not a disease. The distinction drawn by the Examining Division between temporary and permanent ectoparasites is artificial and arbitrary. The treatment of ectoparasites, however long they remain on a host body, is not curing a disease. A more useful distinction is between ectoparasites and endoparasites. The latter constitute a disease; the former do not.
- (4) The law in the EPC countries should be uniform. The decision of the UK Patents Court in *Stafford-Miller Ltd.'s Applications*, 1984 FSR258, should be followed.

The Appellant filed two auxiliary requests with the statement of grounds:

(i) Claim 1 of the first auxiliary request reads:

"1. The use of a pesticidal composition comprising a pesticide admixed with an aliphatic hydrocarbon oil to substantially prevent systemic action of the pesticide in a method for the control of ectoparasitic infestations of pigs comprising the application of the composition to a localised area of the pig's body surface."

(ii) Claim 1 of the second auxiliary request reads:

"1. The use of pesticide admixed with an aliphatic hydrocarbon oil, to substantially prevent systemic action of the pesticide, for the preparation of a pesticidal composition for application to a localised area of a pig's body to control ectoparasitic infestations."

In both requests, Claims 2-11 correspond *mutatis mutandis* to the originally filed Claims 2-11.

IV. In a communication pursuant to Article 110(2) EPC dated 3 February 1986, the Board expressed as its provisional opinion that reference to Articles 52(1) and 52(4) EPC shows that under these Articles, if a method as defined in a claim is in fact a therapeutic treatment, such method must be regarded as not susceptible of industrial application even though the method is in fact used on an industrial scale. Thus the main question to be answered was: is the treatment of ectoparasites on the animal body a therapeutical method? It expressed the provisional opinion

that the treatment of mange and lice is considered to be a medical treatment.

V. In a reply filed on 13 June 1986 the Appellant submitted that a special view of Article 52(4) EPC should be taken, so that Article 57 is given full effect; and that whether or not the claimed method is a therapeutic treatment is not decisive.

VI. The Appellant requests that the impugned decision be set aside and a patent be granted on the basis of the claims according to the main request, alternatively on the basis of the claims according to the first respectively auxiliary request.

#### Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC and is therefore admissible.
2. All three sets of claims satisfy the requirements of Article 123 (2) EPC.
3. The first question to be decided on this appeal is the proper interpretation of the relevant Articles of the EPC, namely Articles 52(1), 52(4) and 57 EPC.
  - 3.1 Article 52 EPC is headed "Patentable inventions", and inter alia provides that:
    - (1) "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."

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

Article 57 EPC provides that "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture".

- 3.2 In the Board's view, the proper interpretation of Articles 52 to 57 EPC, so far as relevant, is as follows:
- 3.3 Article 52 contains provisions which are intended to define the possible subject-matter of European patents. The scheme of this Article is as follows: Paragraph (1) contains a statement of the essential conditions which must be satisfied by an invention if it is to be patentable - namely that
- (i) it is susceptible of industrial application,
  - (ii) it is new,
  - and
  - (iii) it involves an inventive step.

Paragraphs (2) to (4) define certain subject-matters which, even if they satisfy the above three conditions for patentability, are nevertheless excluded from being patentable, as specific exceptions.

Thus paragraph (2) provides that the particular subject-matters defined in (a) to (d) "shall not be regarded as inventions within the meaning of paragraph 1". Similarly paragraph (4) provides that the methods there defined "shall not be regarded as inventions which are susceptible



of industrial application within the meaning of paragraph 1". It is noted that there is a slight difference in wording between paragraphs (2) and (4). However, the effect is in both cases clearly the same: namely to exclude the defined subject-matters from being the subject-matter of a European patent, even if such subject-matter is an invention which satisfies paragraph (1), i.e. it satisfies conditions (i) to (iii) above.

The difference in wording between paragraphs (2) and (4) results from the nature of the subject-matters that are being excluded from patentability in the respective paragraphs. The subject-matters which are set out in paragraph (2) are excluded primarily because they have traditionally been regarded within national patent laws as more in the nature of ideas than industrial manufactures. In contrast, the methods which are set out in paragraph (4) are excluded from patentability, even though such methods are capable of being applied industrially, as a matter of policy. Thus the wording of paragraph (4) is implicitly recognizing that such methods are susceptible of industrial application as a matter of reality, but provides that they "shall not be regarded as" inventions which are susceptible of industrial application, by way of legal fiction.

3.4 Article 53 EPC sets out certain other exceptions to patentability, and need not be considered further.

Articles 54 and 55 EPC define and explain the nature of the requirement for patentability set out in Article 52(1) EPC, that the subject-matter is "new". Similarly, Article 56 EPC defines and explains the nature of the requirement in Article 52(1) EPC that the subject-matter must "involve and inventive step".

3.5 Similarly, Article 57 EPC defines and explains the nature of the requirement in Article 52(1) EPC that the subject-matter is "susceptible of industrial application". In particular, this Article makes it quite clear that under the EPC, agriculture is a kind of industry; and that agriculture methods are therefore, in general, methods which are susceptible of industrial application.

However, the scheme of Articles 52 to 57 as set out above makes it quite clear that even though agricultural methods in general are potentially patentable subject-matter, the particular methods defined in Article 52(4) EPC are excluded from patentability. In other words, for the particular methods defined in Article 52(4) EPC, Article 52(4) takes precedence over Article 57 EPC.

3.6 The excluded methods are:

(i) methods for treatment of the human or animal body by surgery or therapy;

(ii) diagnostic methods practised on the human or animal body.

3.7 The exclusion of such methods from patentability is not a new provision under the EPC. Prior to the coming into force of the EPC, such methods were excluded from patentability under the national laws of many European countries. The policy behind the exclusion of such methods is clearly in order to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents.

3.8 The Board has considered the relevant preparatory documents which led to the EPC. The interpretation of the Articles 52 and 57 EPC set out above appears to be fully consistent

with such documents, in that the object of the provision of Article 52(4) EPC was to exclude from patentability "treatment intended to cure or alleviate the suffering of animals" (see in particular Conference document BR/219/72, para. 27).

4. The submissions in the grounds of appeal will now be discussed with reference to the numbered paragraphs of paragraph III above.
- 4.1 The particular problem which arises in a case such as the present is that the method which is defined by the claims can be applied either to individual animals or to herds of animals. When the method is applied to individual animals it has the nature of a veterinary treatment, and when applied to herds of animals it also has the nature of an industrial activity. There is of course no doubt that the rearing of live stock such as herds of pigs is a farming activity, and that farming is in the broad sense a part of agriculture and therefore in turn an industrial activity for the purposes of the EPC. Thus it is easy, as such, to draw the distinction between individual veterinary treatment on the one hand and large-scale treatment activities normally carried out by a farmer on the other hand - as was put forward by the Appellant. Nevertheless, if the method defined in the claims covers both forms of activity, the drawing of such a distinction does not help the Appellant's case. As discussed in paragraphs 2.2 to 2.5 above, Article 52(4) EPC excludes the methods therein defined from patentability.

It must be recognised that any therapeutic treatment of a farm animal can also be considered as an industrial activity, insofar as farming is clearly an industrial activity, and the medical treatment of disease in both individual farm animals and herds of farm animals is

intended to increase the efficiency of such industrial activity. To prevent the death of a farmyard pig from disease by a medical treatment, or to cure it of a disease by such a treatment and thus to increase its yield of meat, is in each case both an industrial activity and a therapeutic treatment. Clearly the therapeutic treatment of animals is commonly an aspect of agriculture.

- 4.2 The fact that the active ingredient could equally be applied to inanimate loci such as a pig house is irrelevant, because the claims require application to a pig's body.
- 4.3 The Board agrees with the Appellant that the distinction which was drawn by the Examining Division in its Decision between the treatment of temporary and permanent ectoparasites, and the finding that only the treatment of permanent ectoparasites (for example pigs infested with mange lice) has to be considered as a therapeutic treatment of a diseased animal body, has no proper basis in law.

On the other hand, the Board does not agree with the Appellant that there is any proper basis in law for distinguishing between ectoparasites and endoparasites for the purpose of Article 52(4) EPC. The question at issue is not whether endoparasites or ectoparasites are treated but whether the method defined by the claim is a treatment of the animal body for the purposes of Article 52(4) EPC.

Therefore, to summarise, if a claimed method requires the treatment of an animal body by therapy, it is a method which falls within the prohibition on patentability set out in Article 52(4) EPC. It is not possible as a matter of law to draw a distinction between such a method as carried out by a farmer and the same method as carried out by a veterinarian, and to say that the method when carried out by a farmer is an industrial activity and therefore

patentable under Article 57, and when carried out by a veterinarian is a therapeutic treatment not patentable under Article 52(4). Nor is it possible as a matter of law to distinguish between the use of such a method for the treatment of ectoparasites and endoparasites.

- 4.4 A further question to be decided in this appeal is whether, as a matter of fact, the treatment of pigs infested with pig mange is treatment of a disease. The Appellant has submitted that mange is not a disease.

However, in the Board's view it is clear that, contrary to the submission of the Appellant, mange is a disease of the skin which is caused by the presence of parasites. Thus the Shorter Oxford English Dictionary defines mange as "A cutaneous disease occurring in many... animals, caused by an arachnidan parasite". Furthermore, effective treatment of this disease is only possible by treatment of the infected body so as to eradicate the ectoparasites which caused it.

The Examples in the descriptive part of the application in suit are all concerned with the treatment of pigs infested with pig mange (*sarcoptes scabiei*). It is noted that the reference cited by the Appellant - Monnig's "Veterinary Helminthology and Entomology", London 1962, at page 516 states that "Sarcoptic mange is a scheduled disease in most countries".

As a matter of fact, the Board therefore considers that the Examples in the application in suit are each carrying out a method of treatment of diseased pigs' bodies, and that such a method is a method for treatment of the animal body by therapy.

5. Accordingly, in the Board's judgment having regard to the proper interpretation of Article 52(4) EPC, the claimed invention cannot be regarded as "an invention susceptible of industrial application within the meaning of Article 52(1) EPC", and is therefore not patentable.
6. The Appellant has relied upon a case decided by the U.K. Patents Court, *Stafford-Miller Ltd.'s Applications*, 1984 Fleet Street Reports 258, in two respects.
  - 6.1 (i) First the Appellant relies upon the finding of the Court that an infestation of lice cannot "sensibly be described as a bodily sickness, disorder or chronic disease". This finding was primarily in the context of methods for the control of lice on human beings, and was made on the basis of evidence put before the Court by the applicants in that case. The Appellant further submits that no distinction should be drawn between lice and mange mites in this context.
    - (ii) The Appellant also submitted that the Board of Appeal should follow this case in the interest of uniformity of the law in the EPC countries.
  - 6.2 As to (i), the Board's finding set out in paragraph 3.4 above that the treatment of pigs infected with pig mange is a therapeutic treatment of a disease is made on the basis of the evidence before it. The finding of the U.K. Patents Court to the effect that an infestation of lice on human beings is not a disease was based on different evidence, and is therefore not persuasive to the Board.

As to (ii), the legal framework in which the *Stafford-Miller* case was decided must be distinguished from that of the present appeal on the following basis:

- (a) The Stafford-Miller case was not decided under the provisions of the U.K. Patents Act, 1977, whose relevant sections concerning patentability are based upon and intended to have the same effect as Articles 52 to 57 EPC. The case was decided under the U.K. Patents Act, 1949, which did not contain any specific statutory exclusion from patentability of claims to the medical and veterinary treatment of humans and animals.

Under the 1949 Act and the earlier Acts in the U.K., there was a body of case law laid down in decisions of the Patent Office and in appeals from decisions of the Patent Office, to the effect that a method of medical or veterinary treatment of a human or an animal was not "a manner of new manufacture" within the Statute of Monopolies, and was therefore not within the definition of an "invention" in Section 101 of the Patents Act 1949. However, neither the Patent Office nor the Patents Appeal Tribunal or Court when hearing an appeal from a decision of the Patent Office, had the power to decide finally this question of patentability. This limited function of decisions of the Patent Office and of appeals from the Patent Office is set out clearly in Swift's Application, 1962 RPC37, where the headnote says:

"The Court did not decide whether or not the method was a manner of manufacture: but on a preliminary point:

Held, that the function of the Comptroller and the Appeal Tribunal is to refuse to allow to proceed only applications which in no reasonable view could be said to be within the ambit of the Patents Acts and so were plainly without justification".

Thus the function of the Patents Court in the Stafford-Miller case was only to decide whether he claimed invention in that case was possibly patentable: not whether it was actually patentable. The Court's conclusion in the penultimate sentence on page 261 reflects this function: "... I am not sufficiently satisfied that these claims fall on the wrong side of the line as to justify saying at this stage in their life that these patents are incapable of providing a good basis for a sound claim". The Court thus gave the applicants the benefit of its doubt.

In contrast to the function of the Patents Court in the Stafford-Miller case, in the present case the function of this Board is to decide the question of actual patentability of the claims having regard to Article 52(4) EPC.

Thus the Decision in the present case would not cause any lack of uniformity in the law of the EPC countries.

7. The Appellant has also submitted that, even if it is decided that the method of the present application is a therapeutic treatment practical on the animal body, a "special view" should be taken of Article 52(4) so that Article 57 EPC is given full effect. He submits that a justification for taking such a special view can be derived by analogy from Decision Gr 05/83 of the Enlarged Board of Appeal in the "Second Medical Indication" case (OJ EPO 3/1985 page 64) at paragraph 22. In that case the Board found it necessary to take a "special view" of the concept of "state of the art" defined in Article 54(2) EPC, in order to overcome "the problem concerning the novelty of the invention" which that Article presented, in connection



with the allowability of claims directed to the use of substance or composition for the manufacture of a medicament for a specified new therapeutic application.

In the Board's view the "Second Medical Indication" case does not provide any justification for taking the special view of Article 52(4) EPC which the Appellant requests, in order to enable allowance of claims directed to "a method for treatment of the animal body by therapy", because such claims are expressly excluded from patentability by Article 52(4) EPC, as discussed above.

The submission of the Appellant is in effect that Article 57 EPC should take precedence over the express provision of Article 52(4) EPC, in the event of conflict between them. However, in the Board's view as discussed in paragraphs 3.2 to 3.5 above, that is not the proper interpretation of the EPC.

8. The Appellant has further submitted - with reference to Benkart, Patentgesetz, 7. Auflage, 1981, page 265 - that methods for combatting pests are susceptible of industrial application under German case law. The Board as set out above however has decided that the method according to Claim 1 is to be interpreted as a method of medical treatment and not as a method for combatting pests.

9. First auxiliary request.

In the Decision Gr 05/83 (Second Medical Indication) the Enlarged Board of Appeal decided (see points 11-13) that:

"a claim directed to the "use of a substance or composition for the treatment of the human or animal body by therapy" is in no way different in essential content from a claim directed to "a method of treatment of the human or animal body by therapy with the substance or composition". The

difference between the two claims is one of form only and the second form of claim is plainly in conflict with Article 52(4) EPC. Since this is so, no patent can be granted including any such claims: Article 97(1) EPC".

It follows that the claims according to the first auxiliary request are not in substance different from the claims according to the main request, and are therefore not patentable for the same reasons.

10. Second auxiliary request.

The claims according to the second auxiliary request are in line with those allowed by the decision in the "Second Medical Indication" case. However, the use of insecticides in treating ectoparasites is admittedly known (see the description page 1, second para.). Furthermore, even though the claims are directed to a particular formulation of pesticide, applied by a particular mode of administration to a particular animal, there is no disclosure of a new medical indication.

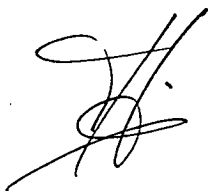
For these reasons, the Board sees no basis for allowing this request either.

Order

For these reasons it is decided that:

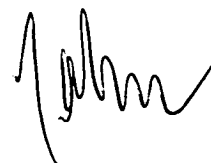
The appeal is dismissed.

The Registrar



F.Klein

The Chairman



K.Jahn