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**Datasheet for the decision
of 10 August 2006**

Case Number: T 0173/06 - 3.3.04

Application Number: 00937086.7

Publication Number: 1191938

IPC: A61K 35/64

Language of the proceedings: EN

Title of invention:
Immunity generation

Applicant:
Immune Macro - Biotic Technology UK Limited

Opponent:
-

Headword:
Immunity generation/IMMUNE MACRO-BIOTIC TECHNOLOGY

Relevant legal provisions:
EPC Art. 54, 82, 111(1), 123(2)
EPC R. 68(2), 86(4)

Keyword:
"Unsearched subject matter (no)"
"Lack of unity of invention (no)"
"Novelty (yes)"
"Remittal (yes)"

Decisions cited:
W 0011/89, W 0006/91, W 0008/94, W 0006/97, W 0017/03,
T 0708/00, T 0274/03, G 0005/83

Catchword:
-

Case Number: T 0173/06 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 10 August 2006

Appellant: Immune Macro - Biotic Technology UK Limited
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted 29 August 2005
refusing European Patent application
No. 00937086.7 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chair: U. Kinkeldey
Members: R. Gramaglia
D. S. Rogers

Summary of Facts and Submissions

I. European patent application No. 00 937 086.7 published as WO 00/74693 with the title "Immunity generation" was filed with 12 claims reading as follows:

"1. A method for the manufacture of a medicament for immunity generation and/or treatment and/or prevention of allergies, which method includes the use of insect tissues and/or larval forms and derivatives of insects."

"2. A medicament for the provision of immunity to bacterial and viral disease and/or allergies and/or tumours, said medicament comprising insect tissues and/or larval forms and derivatives of insects."

"3. A medicament as claimed in Claim 2, which is in a form which permits its ingestion, digestion and assimilation."

"4. A medicament as claimed in Claim 2, which is in a form which permits its injection into the subject to which or whom the immunity is to be given."

"5. A medicament as claimed in Claim 2, which is in a form which permits its absorption transcutaneously."

"6. A method of recycling biological waste which includes the use of insects, including larval and other life forms, to produce either a medicament having immunity-generating properties or a food source which has immunity-generating properties."

"7. A method as claimed in Claim 6, in which the biological waste is or includes sewage."

"8. A method as claimed in Claim 6, in which the biological waste is or includes animal offal."

"9. A method as claimed in Claim 6, in which the recycling of the biological waste material is effected on land which is enriched by the recycling process."

"10. A method of producing a food source which includes the use of insects and their larvae which act as carriers providing immunity generation as well as protein, energy and biologically active beneficial materials."

"11. A method of raising chickens, which includes feeding the chickens on the food source produced by the method of Claim 10."

"12. A method of promoting the growth of plants in soil and increasing the resistance of the plants to fungal attack, which includes the addition of the end product of the method of Claim 6 to the soil."

II. With the letter dated 7 February 2004 the applicant filed new claims 1 to 5:

"1. A method for the manufacture of a medicament for immunity generation and/or treatment and/or prevention of allergies, which method includes the use of insect tissues and/or larval forms and derivatives of insects, characterised in that the insects have been fed on a food containing pathogens."

"2. A method as claimed in Claim 1, characterised in that the food containing pathogens is biological waste."

"3. A method as claimed in Claim 1, characterised in that the larval forms of insects are maggots."

"4. A medicament made by the method claimed in any one of the preceding claims."

"5. A method of raising chickens, which includes feeding the chickens on the medicament of Claim 4."

III. In an official letter dated 18 October 2004, the examining division raised the objection that the newly filed claims were not admissible under Rule 86(4) EPC because (i) they related to unsearched subject-matter and (ii) they did not combine with the originally claimed and searched invention to form a general inventive concept. This letter also referred to the communication of 16 June 2003. This communication stated that claims 1 to 4 related to subject-matter which was neither new nor inventive over D5 and/or D6. In addition claim 5 was a method for the treatment of the human body and hence unallowable under Article 52(4) EPC. Even if claim 5 was properly reformulated as a "second medical use", then it would not be inventive.

IV. With a decision dated 29 August 2005, the application was refused according to Article 97(1) in conjunction with Rule 86(4) EPC.

V. The appellant (applicant) lodged an appeal against this decision.

VI. Oral proceedings were held on 10 August 2006, during which the appellant filed new claims 1 to 4:

"1. A method for the manufacture of a medicament for immunity generation, which method includes the use of insect tissues and/or larval forms and derivatives of insects, characterised in that the insects have been fed on a food containing pathogens to induce the production in the insects of peptides corresponding to a specific immune response."

"2. A method as claimed in Claim 1, characterised in that the larval form of insects are maggots."

"3. A medicament made by the method claimed in either of the preceding claims."

"4. A method of raising chickens, which includes feeding the chickens on the medicament of Claim 3."

VII. The following documents are cited in the present decision:

D1 DE-A-195 43 513;

D2 DE-A-42 11 745;

D3 DE-A-41 11 782;

D4 US-A-4 405 602;

D5 DE-A-36 11 791;
D6 US-A-3 814 057;
D7 GB-A-874 297;
D8 EP-A-1 006 124.

VIII. The appellant's arguments were essentially as follows:

Article 123(2) EPC

- New claim 1 was based on claim 1 as filed with the additional feature "the insects have been fed on a food containing pathogens, to induce the production in the insects of peptides corresponding to a specific immune response". This feature was based on page 5, second paragraph of the published WO application.

Unsearched subject-matter (Rule 86(4) EPC)

- According to decisions T 708/00 dated 5 December 2003 and T 274/03 dated the 8 July 2004, amended claims could only be refused on the basis of Rule 86(4) EPC if the subject matter of the claims as originally filed and that of the amended claims was such that, had all claims originally been filed together, a further search fee would have been payable. However, this was not the case.

Novelty

- Claim 1 was in the form of a second/further medical use of an "insect tissues and/or larval forms and derivatives of insects" for making a medicament for "immunity generation". The mechanism by which "immunity generation" was achieved according to claim 1 was one wherein "the insects have been fed on a food containing pathogens, to induce the production in the insects of peptides corresponding to a specific immune response". None of the cited documents disclosed the above feature.

IX. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution.

Reasons for the Decision

Article 123(2) EPC

1. New claim 1 is based on claim 1 as filed with the feature "the insects have been fed on a food containing pathogens to induce the production in the insects of peptides corresponding to a specific immune response". This feature can be found on page 5, second paragraph of the published WO application.
Claim 2 is based on page 6, second full paragraph.
Claim 3 is based on page 1, under "Summary of the Invention". Claim 4 is based on claim 11 as filed.
Therefore, new claims 1-4 do not infringe Article 123(2) EPC.

Unsearched subject-matter (Rule 86(4) EPC)

2. The examining division refused the application according to Article 97(1) in conjunction with Rule 86(4) EPC because claims 1 to 5 filed with the letter of 7 February 2004 (i) related to unsearched subject-matter and (ii) did not combine with the originally claimed and searched invention to form a general inventive concept (lack of unity), the latter deficiency being the second condition which had also to be fulfilled for amended claims to be rejected under Rule 86(4) EPC.

3. As regards objection (i) above (unsearched subject-matter), the examining division considered that the subject matter of the above mentioned claims 1 to 5 was not claimed as such in the original application because the methods and medicaments according to original claims 1 to 5, 9 and 10 did not comprise the feature that the insects had to be fed with contaminated material.

4. However, claims 1 to 5 filed with the letter dated 7 February 2004 underlying the decision under appeal, which comprise the feature that "the insects have been fed on a food containing pathogens" represented a more restricted version of the searched claims devoid of said feature. This has been acknowledged by the examining division in paragraph 1.1₁ of its communication dated 18 October 2004. Thus a search for any documents disclosing a relationship between, on the one hand, insect tissues and/or larval forms and derivatives of insects and, on the other hand, immunity generation would also have returned documents

disclosing tissues and/or larval forms and derivatives of insects "fed on a food containing pathogens" for generation of immunity. It is not apparent why the search examiner should have overlooked/discarded such documents, all the more so as the application as filed (see in particular claim 2, page 5, lines 1-3 and the long list of pathogens on pages 10-13) suggested that the "immunity" referred to in all the claims as filed had to be directed against virus and bacteria.

5. This board's view is supported by the fact that the search report indeed cites (inter alia) document D5, disclosing tissues and/or larval forms and derivatives of insects possibly "fed on a food containing pathogens" for generation of immunity (see points 14 and 15 infra). In conclusion, claims 1 to 5 filed with the letter dated 7 February 2004 and comprising the feature that "the insects have been fed on a food containing pathogens" could not relate to "unsearched subject matter".
6. The conclusion arrived at by the board under point 5 supra extends to the now claimed subject-matter, which also includes the feature "the insects have been fed on a food containing pathogens".
7. In connection with objection (ii) above (lack of unity of invention of the amended claims with the originally claimed and searched invention), the examining division considered that "the common concept linking the numerous aspects of the application (e.g., the general use of untreated insects larvae/tissues or derivatives (a) for preparing medicaments, including their use to generate immunity or for treating allergy, (b) as food

- sources, or (c) for recycling biological waste) was already known from the state of the art" (i.e. documents D1 to D7).
8. To determine whether or not there is unity of invention requires as a precondition an analysis of the technical problem or problems underlying the respective groups of inventions (see decision W 11/89, OJ EPO 1993, 225, followed by numerous decisions including e.g. decision W 6/91 of 3 April 1992; decision W 8/94 of 21 November 94; decision W 6/97 of 18 September 1997 and decision W 17/03 of 20 September 2004).
9. However, there is no discussion in the appealed decision of either the technical problem or problems underlying the respective groups of inventions. Nor is there any discussion as to why the subject-matter of claims 1 to 5 filed with the letter dated 7 February 2004 differed from that of the searched claims. Therefore the appealed decision fails to fulfil the requirement of Rule 68(2) EPC that decisions of the EPO shall be reasoned.
10. Moreover, the examining division apparently did not pay any attention to the fact that all the independent claims as filed, including those relating to "recycling of biological wastes" and "producing a food source" relied on the common feature of generating "immunity" (for independent claim 12: "resistance of the plants to fungal attack"), which was the idea behind the present application (see also the title: "Immunity generation"). Nor has the examining division noted that immunity generation was also the biological effect to be achieved according to claims 1 to 5 underlying the

decision under appeal. Therefore, the board does not adhere to the view of the examining division that the amended claims lacked unity with the originally claimed and searched invention.

11. The appellant filed at the oral proceedings before the board new claims 1 to 4 in replacement of any previous claims (see paragraph VI supra). It is the board's view that the objections of lack of unity raised against the originally claimed and searched invention for the same reasons given above do not apply to these claims either because immunity generation is also the biological effect to be achieved according to present claims 1 to 4.

Novelty

12. Claim 1 is in the form of a second/further medical use of "insect tissues and/or larval forms and derivatives of insects" for making a medicament for "immunity generation". The mechanism by which "immunity generation" is achieved according to claim 1 is one wherein "the insects have been fed on a food containing pathogens, to induce the production in the insects of peptides corresponding to a specific immune response". The relevant issue is whether or not this use relates to a novel medical use in the sense of decision G 5/83 (OJ 1985, 064).

Documents D1, D2, D3, D4, D6 and D7

13. Document D1 (see column 1, lines 20-27) discloses a medicament obtained from mosquito saliva (a "derivative of insects") for killing human immunodeficiency virus

(HIV), not for "immunity generation". Document D2 (see column 1, lines 24-29) discloses the use of propolis, i.e., a natural resin from wounded trees, not a "derivative of insects" (in spite of its being collected by bees) as a medicament for inhibiting the release of inflammatory mediators. Document D3 (see column 1, lines 9-17) describes a solution in ethanol of "Bienenkittharz", i.e., propolis, for use as an oral immunostimulating agent. Document D4 (see column 1, line 6 and column 3, line 39) is concerned with a product prepared from bee larvae for use in human nourishment and as poultry food. Document D6 (see column 2, lines 21-25) relates to a product made from fly pupae and its use for feeding chicks and hens. Document D7 (see page 1, line 20) discloses a product comprising dried insects (a "derivative of insects") and its use to feed birds. These documents thus do not disclose the relationship stated in present claim 1 between "insect tissues and/or larval forms and derivatives of insects" and "immunity generation", let alone the feature that "immunity generation" is achieved via induction of the production in the insects fed on a food containing pathogens or peptides corresponding to a **specific** immune response.

14. In conclusion, the use of "insect tissues and/or larval forms and derivatives of insects" as claimed in claim 1 is not anticipated by any of the disclosures of documents D1, D2, D3, D4, D6 or D7.

Document D5

15. This document discloses insect tissues and/or larval forms and derivatives of insects in the context of the

generation of an immune response (see column 2, lines 31 to 34). However, it cannot be directly and unambiguously derived from the passage in column 2, lines 31 to 34 that immunity generation ("günstig das Immunsystem...beeinflussen") is achieved via induction in the insects fed on a food containing pathogens of the production of peptides corresponding to a **specific** immune response. This is because the skilled person reading column 2, lines 31 to 34 of document D5 is not taught whether this immunity generation follows from the mechanism stated in claim 1 or it is the consequence of e.g., a better food, which made the animals healthier and thus more resistant to pathogen attacks. Even assuming that the presence of pathogens is implicitly disclosed in document D5 in view of the inevitable presence in any waste of degrading bacteria, no conclusion can be derived either from document D5 as to whether the immune response is specific for a given pathogen, as required by present claim 1. In summary, document D5 does not directly and unambiguously disclose the further medical use of "insect tissues and/or larval forms and derivatives of insects" according to present claim 1.

Document D8

16. This document representing prior art in the sense of Article 54(3) EPC also discloses insect derivatives in the context of the generation of an immune response. However, immunity generation takes place according to document D8 via the activation of natural killer cells able to non-specifically kill malignant or virus-infected cells (see page 3, paragraph [0024]). Example 3 indeed (see page 6, lines 33-34) shows the

killing of hepatoma and K562 cancer cells by these natural killer cells. But document D8 does not directly and unambiguously disclose the further medical use of present claim 1, according to which immunity generation occurs because "the insects have been fed on food containing pathogen, to induce the production in the insects of peptides corresponding to a **specific** immune response."

17. In conclusion, the medical use of "insect tissues and/or larval forms and derivatives of insects" as claimed in claim 1 is also not anticipated by any of the disclosures of documents D5 or D8.

Inventive step

18. The examining division also appears to have rejected the application on the basis that claim 5 was not inventive over D5 and/or D6. The discussion of this issue in paragraphs 5.1 and 5.2 of the decision indicates that the examining division has in fact found that claim 5 was not novel over D5 or D6 as it found that D5 or D6 "...anticipates both the novelty and the inventive step of...present claim 5" (emphasis added). In addition to the curious concatenation of "anticipates" with "inventive step", there is no hint of any application of the problem-solution approach, or indeed of any systemic approach, to the question of inventive step. Thus as to the issue of inventive step the examining division has simply stated a conclusion without reasoning. It has thus again failed to fulfil the requirement of Rule 68(2) EPC that decisions be reasoned. Given that the claims before the board differ from those before the examining division and given the

complete lack of any reasoned decision by the examining division on inventive step, the board will not consider the issue any further.

Remittal

19. The present application was rejected for reasons of non-compliance with Rule 86(4) EPC and was based on claims different from the claims presently on file. For the purpose of the present decision the board has already examined the claims as to whether or not they fulfil the requirements of Articles 123(2) and 54 EPC (see points 1 and 12 to 17 above), but, in order not to deprive the applicant of his right to have his invention examined by two instances, and in accordance with the established jurisprudence of the boards of appeal, the board uses its discretion under Article 111(1), second sentence, EPC, and remits the case to the first instance for further prosecution to consider the remaining issues. In particular, the board observes that the present application contains no worked example showing that immunity generation actually takes place by following the technical information provided by the application. Therefore the issue of whether or not the application satisfies the requirements of Article 83 EPC will *inter alia* need to be dealt with. In addition the first instance will need to carry a proper analysis of whether or not the claims satisfy the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of claims 1 to 4 of the main request filed at the oral proceedings.

The Registrar:

Chair:

P. Cremona

U. M. Kinkeldey