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D E C I S I O N
of 4 April 2006

Case Number: T 0708/02 - 3.3.01

Application Number: 95931304.0

Publication Number: 0781094

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Language of the proceedings: EN

Title of invention:
Control of sea lice in fish

Patentee:
VERICORE LIMITED

Opponent:
Alpharma AS
Akzo Nobel N.V.

Headword:
Sea lice infestation/VERICORE

Relevant legal provisions:
EPC Art. 54(2)

Keyword:
"Novelty (no) - no new therapeutic application over the prior art"

Decisions cited:
G 0005/83, T 0019/89, T 0254/93, T 0469/94, T 0233/96,
T 1031/00, T 0486/01, T 1020/03

Catchword:

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Case Number: T 0708/02 - 3.3.01

D E C I S I O N
of the Technical Board of Appeal 3.3.01
of 4 April 2006

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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted 9 April 2002
rejecting the opposition filed against European
patent No. 0781094 pursuant to Article 102(2)
EPC.**

Composition of the Board:

Chairman: A. Nuss
Members: P. P. Bracke
 D. Rogers

Summary of Facts and Submissions

I. The appeal lies from the Opposition Division's decision to reject the oppositions against European patent No. 0 781 094.

II. The Respondent (Proprietor of the patent) filed with telefax of 3 March 2006, as a Main request, a set of six claims, with the independent claims reading:

"1. The use of a pyrethroid compound selected from cypermethrin, high-cis-cypermethrin and deltamethrin for the manufacture of a composition for the treatment of the chalimus and copepodid phases of sea lice infestation of fish."

"2. The use of a pyrethroid compound selected from cypermethrin, high-cis cypermethrin and deltamethrin for the manufacture of a composition for the prophylaxis of pre-adult and adult sea lice infestation of fish."

With telefax of 20 March 2006 the Respondent filed, as an Auxiliary request, a set of five claims. The wording of the sole independent Claim 1 was identical with the wording of Claim 2 according to the Main request filed with telefax of 3 March 2006.

III. Oral proceedings before the Board took place on 4 April 2006.

IV. The Appellants (Opponents) contested the novelty of the claimed use over the disclosure of document

(7) WO 92/16106,

since it described the use of the same compounds for the treatment of the same subjects suffering from the same disease as the claimed use.

V. The Respondents submitted that the chalimus and copepodid phases of sea lice were distinct from the mature phases of sea lice and, thus, that in the claimed use not only different subjects but also different diseases were treated as the ones described in document (7).

VI. The Appellants requested that the decision under appeal be set aside and that the European patent No. 0 781 094 be revoked in its entirety.

The Respondent requested that the patent be maintained on the basis of the Main or Auxiliary request filed with telefax of 3 March 2006 and 20 March 2006 respectively.

Reasons for the Decision

1. The appeals are admissible.
2. Article 123(2) and (3) EPC

Since the Board came to the conclusion that none of the requests meets the requirement of novelty, it is not necessary to give any reasoning as to whether the requirements of Article 123(2) and (3) EPC are met.

3. *Main request*

3.1 Novelty of Claim 1

3.1.1 It was not contested that the use of *inter alia* cypermethrin for the manufacture of a composition for the treatment of sea lice infestation in sea fish is described on page 2, lines 19 to 23, and in Claim 1 of document (7). However, it was contested that such disclosure would be novelty destroying for the presently claimed use (see point IV above).

3.1.2 According to decision G 5/83 (OJ EPO 1985, page 64), claims directed to the use of a substance for the manufacture of a medicament for a specified new and inventive therapeutic application are allowable, even when the process of manufacture as such does not differ from known processes using the same active ingredient. However, according to the further developed jurisprudence of the Boards of Appeal of the EPO, a new property of a known substance or a new technical effect achieved by a known substance does not necessarily translate into a novel use. For a therapeutic application to be construed as a novel further medical use, this new property or this new technical effect of a known substance must lead to a truly new therapeutic application, which is

- the treatment of a different pathology, or
- the treatment of the same pathology with the same substance, however, when carried out on a new group of subjects distinguishable with respect to its

physiological or pathological status from the previously suggested subjects for such treatment

(see, for example, decisions T 19/89 OJ EPO 1989, page 24, point 8 of the reasons; T 233/96 of 4 May 2000, point 8.7 of the reasons; T 1031/00 of 23 May 2002, point 2.3 of the reasons; T 486/01 of 3 September 2003, point 8 of the reasons; and T 1020/03 of 20 October 2004, point 8 of the reasons).

3.1.3 Since what is claimed in the present case concerns the treatment of the chalimus and copepodid phases of sea lice infestation of fish, the Respondent submitted that the presently claimed use differed from the use described in document (7) by the fact that not sea lice as such were treated, but specific developmental phases thereof, namely the chalimus and copepodid phases, and thus that a different pathology was treated.

3.1.4 Document (7) is essentially related to the finding that *inter alia* cypermethrin is highly effective in the control of sea lice in sea fish while being much less toxic to the fish themselves and that, therefore, cypermethrin may be used in the treatment of sea fish suffering from sea lice infestation (see page 2, lines 7 to 18). Thus, the **pathology** treated according to document (7) is the **sea lice infestation** of subjects suffering thereof.

It was not contested, that, according to the common general knowledge, as presented in Chapter 3 "Supplemental descriptions of the developmental stages of *Lepeophtheirus salmonis* Kroyder, 1837) (Copepoda: Caligidae) of document

(9) Pathogens of wild and farmed fish. Sea Lice, Ellis Horwood, New York , 1993, pages 30 to 47,

sea lice develop in ten stages, namely two free-swimming nauplius stages, one free-swimming infective copepodid stage, four attached chalimus stages, two preadult stages and the adult (see the last full paragraph on page 30). This common general knowledge is also confirmed in paragraph [0002] of the patent in suit, stating that sea lice in the copepodid phase attach themselves to the body of the fish and develop through four immature chalimus phases before becoming pre-adults about 2 to 4 weeks after the initial infestation.

Therefore, the only difference in the pathological treatment described in document (7) with the one according to the claimed use could only be seen in the finding that the effect of cypermethrin on sea lice is not only due to its effect on the mature stages of sea lice but also on the premature stages thereof. Such finding, however, cannot be considered as a distinguishing feature for the pathological treatment, but only as an explanation of an effect obtained when using cypermethrin in the treatment of sea fish suffering from sea lice infestation.

However, according to the jurisprudence of the Board of Appeal, the mere explanation of an effect obtained when using a known substance, even if the explanation relates to a pharmaceutical effect which was not known to be due to that substance, cannot confer novelty on a known treatment if the skilled person was already aware

of the occurrence of the desired effect when applying the known treatment (T 254/93 OJ EPO 1998, page 285, point 4.8 of the reasons).

Consequently, the finding that cypermethrin is not only effective on the mature developmental stages of sea lice but also on immature developmental stages, such as the chalimus and copepodid phases, does not result in a different pathology being treated.

3.1.5 The Respondent further submitted that the subjects treated as described in document (7) can be distinguished from those treated according to the claimed use, since the sea fish treatment described in document (7) was conducted on sea fish having mature sea lice attached thereon, whereas the sea fish treatment according to the claimed use was conducted on sea fish having pre-mature sea lice attached thereon.

3.1.6 Since a group of subjects can only be considered novel if the subjects are clearly distinguishable with respect to their physiological or pathological status (see point 3.1.2), the question arises, thus, whether the physiological or pathological status of the treated fish according to the disclosure of document (7) is different from the physiological or pathological status of the fish treated according to the claimed use.

As the Respondent himself submitted in the first paragraph on page 3 of the letter of 3 March 2003, it is the object of the claimed use to find an active substance which is capable of killing or disabling immature sea lice at a concentration at which fish do not experience high mortalities. Therefore, the

subjects treated are fish attacked by sea lice. Whether the fish is attacked by mature sea lice or immature sea lice does not have any effect on the functioning of the living organism and thus on the physiological status of the fish.

Moreover, independent of the fact whether the fish is attacked by mature or premature sea lice, the pathology treated according to the claimed use is the sea lice infestation which the fish is suffering from. Therefore, also the pathological status of the fish treated according to the claimed use is the same as the pathological status of the fish treated according to the use described in document (7).

3.1.7 Since thus neither a different pathology as in document (7) nor a new group of subjects distinguishable from the fish described in document (7) is treated according to the claimed use, Claim 1 is not novel over document (7).

3.2 Novelty of Claim 2

3.2.1 Claim 2 differs from Claim 1 in that the composition is used for the prophylaxis of pre-adult and adult sea lice infestation of fish.

3.2.2 Referring to the second paragraph in point 5.2 of T 469/94, the Respondent submitted, that prophylaxis is not identical with the prevention of the disease itself, but simply the prevention of the acute phase of a chronic disease. Since the prevention of the acute phase of sea lice infestation of fish was not described

in document (7), the claimed use was novel over the disclosure of document (7).

- 3.2.3 However, the passage referred to in T 469/94 should be taken in its context. The complete sentence reads:

"Likewise in the case of the prophylactic use of choline envisaged in (2) for muscle rheumatism or muscle troubles arising from thyroidal diseases , the prophylaxis does not appear to mean the prevention of the disease itself, but simply the prevention of the acute phase of a chronic disease."

Thus it follows that the meaning given to the term "prophylaxis" is not the generally accepted meaning but a specific one adapted to the specific situation therein.

In the present case, the Board does not see any reason to deviate from the generally accepted meaning of "prophylaxis", namely the preventive treatment of diseases.

- 3.2.4 Therefore, the question arises whether the preventive nature of a treatment can be a distinguishing feature restoring novelty to Claim 2.

Since the preventive treatment defined in Claim 2 does not differ from the treatment according to Claim 1, by the preventive nature of the treatment neither a different pathology nor a new group of subjects is treated and, thus, Claim 2 is not novel over the

disclosure of document (7) for the reasons given for Claim 1.

4. *Auxiliary request*

Since Claim 1 is identical with Claim 2 of the Main request, document (7) is considered to be novelty-destroying for the reasons given in point 3 above.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

N. Maslin

A. Nuss