

Re Item I

Basis of the opinion

Present claims 1-12, 14-23, 25-27, and 29-33 now encompass any compound of the formula R^1-S-R^1 , wherein R^1 is a C_1-C_4 alkyl, C_2-C_3 alkenyl, or C_2-C_3 alkynyl, whereas the originally filed application (see p.4-7 and the examples) only discloses compounds of the generic formula $R^1-S-S-R^1$ and the very specific compound diallyl sulfide. Thus, the subject-matter of said claims does not meet the requirements of Art. 34 (2) b EPC. For that reason, **no** opinion will be provided for sulfide compounds of the general formula R^1-S-R^1 , wherein R^1 is a C_1-C_4 alkyl, C_2-C_3 alkenyl, or C_2-C_3 alkynyl, except for than diallyl sulfide.

Remarks:

- of course, the above objection does not apply to **disulphide** compounds.
- should the Applicant revert to the previous formulation, lack of clarity should be avoided since diallyl sulfide does not fall under the generic R^1-S-R^1 formula.

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention because methods for the control of sea lice using semiochemicals are known in the art, see item V below. Thus, the use of compounds in such a method can not serve as a common inventive concept. It follows that each invention is based on the type of chemical or plant extract used in the method. On this aspect, it is noted that there appears to be no similarities between the chemical compounds present in garlic, lavender, rosemary, bog myrtle, and isothiocyanates. Thus, each of these plants/compounds is considered to provide a separate invention. And this, even if the Applicant formulated new claims, which separate the inventions. It follows that the present application lacks unity in the meaning of R.13 PCT. The following 5 inventions have therefore been identified:

- 1) claims 1-35: Method of preventing sea lice infestation in farmed fish, using garlic or compounds of formula (I) or diallyl sulfide, and fish feed comprising such compounds;
- 2) claims 36-56: Method of preventing sea lice infestation in farmed fish using rosemary, and fish feed comprising rosemary or extract thereof;

- 3) claims 57-77: Method of preventing sea lice infestation in farmed fish using lavender, and fish feed comprising lavender or extract thereof;
- 4) claims 78-98: Method of preventing sea lice infestation in farmed fish using bog myrtle, and fish feed comprising bog myrtle or extract thereof;
- 5) claims 99-146: Method of preventing sea lice infestation in farmed fish, using compounds of formula (II), and fish feed comprising such compounds.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Since all fees have been paid by the Applicant, the present opinion/report deals with all 5 inventions.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

V.1 Reference is made to the following documents:

- D1 ROTH M ET AL: "Current practices in the chemotherapeutic control of sea lice infestations in aquaculture: A review", Journal of Fish Diseases, vol. 16, no. 1, 1 January 1993, pages 1-26, XP009146063
- D2 WO 2004/084645 A2 (STONE ISLAND HDGS LTD [GB]) 7 October 2004
- D3 DE 200 10 027 U1 (RENDLE M [DE]) 28 September 2000
- D4 KR 2009 0093518 A (GYEONGGI DO [KR]) 2 September 2009
- D5 WO 2008/049437 A1 (BIOFIBER DAMINO AS [DK]) 2 May 2008
- D6 GB 2 388 544 A (UNIV ABERDEEN THE [GB]) 19 November 2003
- D7 US 5 504 081 A (LOEHR R [DE] ET AL) 2 April 1996
- D8 DATABASE WPI, Week 199039, Thomson Scientific, London, GB; AN 1990-294657, XP002638541 & JP 2 207758 A (TAIYO KAGAKU KK) 17 August 1990

- D9 WO 2004/091307 A2 (ADVANCED BIONUTRITON CORP [US]; HAREL M [US]) 28 October 2004
- D10 WO 00/59316 A1 (EWOS LTD [GB]) 12 October 2000
- D11 US 2005/266052 A1 (BARTLETT B [AU] ET AL) 1 December 2005
- D12 EP 1 208 751 A1 (NIPPON SUISAN KAISHA LTD [JP]) 29 May 2002
- D13 US 2008/026083 A1 (REYNOLDS MJ [AU]) 31 January 2008
- D14 SYLVESTRE M., LEGAULT J., DUFOUR D., PICHETTE A.: "Chemical composition and anticancer activity of leaf essential oil of Myrica gale L.", PHYTOMEDICINE, vol. 12, no. 4, 2004, pages 299-304, XP002638542
- D15 GB 2 210 616 A (EGYT GYOGYSZERVEGYESZETI GYAR [HU]) 14 June 1989
- D16 US 3 662 069 A (DITTMAR BI [US]) 9 May 1972
- D17 US 2002/164384 A1 (YOSHPA M [US]) 7 November 2002

The following document was not cited in the international search report. A copy of the document is appended hereto.

- D18 US 5 139 791 A (NAKAJIMA K [JP] ET AL) 18 August 1992

V.2 Novelty and inventive step

V.2.1 **Invention 1**: based on garlic and compounds according to formula (I)

First, it is considered that garlic comprises the compounds according to formula (I) mentioned in e.g., claim 11. The use of garlic in the prior art is therefore considered to be an **implicit** disclosure of all these compounds. This is because when garlic is administered, these compounds are also administered.

Document D1 discloses the use of garlic-coated salmon pellets in an attempt to reduce lice numbers in salmon (see p.19), as well as the use of garlic in several attempts (p.19 and p.2). It follows that this document takes away the novelty of present claims 14-16, 21-24, 25-28, and 30-35 (Art. 33 (2) PCT). Further, the additional technical features of claim 27 are options which are obvious to a skilled person having knowledge of that document, thus are devoid of inventive step (Art. 33 (3) PCT). This opinion is taken, even though the attempt reported in D1 was apparently unsuccessful, since independent claim 1 of the present request does not require that the treatment is efficacious. First, coated salmon pellets were indeed prepared, thus product claims 25-29 are unambiguously impacted for novelty. Second, these pellets were indeed used in a method to reduce lice infestation in salmons. Additionally, the technical features of claim 29 are considered an obvious option, which can be obtained through simple routine trial-and-error tests in order to obtain the same effect. Said claim 19 therefore does not involve an inventive step.

Document D1 also discloses the successful use of minced garlic to control *Capillaria* nematodes in carp (also on p.19). Thus, this passage renders the subject-matter of claims 25-29 and 31-35 devoid of inventive step, and that of claim 30 not new.

Document D2 discloses the use of allicin, a compound which is **not** encompassed by the formula (I), in the reduction of parasites associated with fish farming (p.6 I.6-9). Thus, this document is now considered to not be relevant for novelty and inventive step.

Document D3 discloses the use of onion, optionally in combination with garlic, as a vermifuge in farmed fish, when incorporated at 0.1 to 10% in feed. This document therefore takes away the novelty of claims 14, 21-24, 25-29, 30, and 31-35 and renders that of claims 15-19 devoid of inventive step.

Document D4 discloses the use of garlic as e.g., immune stimulant, in sturgeon, when incorporated at 0.1 to 1% in feed. Thus, it is the use of garlic for "reducing the infestation or infection of a parasite in a fish". This document therefore takes suggests the subject-matter of claims 14, 21-24, 25-29, 30, and 31-35.

Document D5 discloses the use of allicin or alliin, two compounds which are **not** encompassed by formula (I), as antibacterial and antidiarrheal agents, at a range of 0.0001 to 0.05%. This document is therefore not relevant for novelty.

Document D8 discloses the use of garlic as well as of diallyldisulfide specifically, to prevent bacterial infections in fish. Thus, this document takes away the novelty of claims 14, 21-24, and 25-28, and renders that of claims 15-19 and 29 devoid of inventive step.

Document D9 discloses the use of many compounds and ingredients, including garlic oils and extracts (§61), in the control of parasitic and bacterial infections of the fish. Thus, this document takes away the novelty of claims 14, 21-24, 25-28, and 30, and renders that of claims 15-20 and 29 devoid of inventive step.

Document D10 discloses the feeding of fish with e.g., garlic (p.3 l.15, p.4 l.20) for influencing the flavour of that fish's meat. Thus, this document takes away the novelty of claims 25-29 in so far as they concern the first invention.

Document D18 discloses the incorporation of sulfide and disulfide compounds, such as diallyl disulfide and diallyl sulfide, in the feed of aquatic animals for the improvement of feed intake (col.1 l.39-43, col.2 l.57-68, most of the compounds listed on col.7 l.42 - col.8 l.68). Thus, this document takes away the novelty of present claims 25-28.

V.2.2 Invention 2: based on rosemary

Document D9 discloses the use of many compounds and ingredients, including rosemary oils and extracts (§46), in in the feed of aquatic animals for the control of parasite and bacterial infections, especially, aquatic infectious diseases in species such as fish (§40). Thus, this document takes away the novelty of claims 51-54 (see also VIII.1) and 56. There appears to be no inventive step for the change of the mode administration from feed to water, or for a dose range in the feed. Thus, the subject-matter of claims 43-50 and 55 does not involve an inventive step.

Document D10 discloses the feeding of fish with e.g., rosemary (p.3 l.15, p.4 l.20) at e.g., 0.05% (p.6 l.23) for influencing the flavour of that fish's meat. Thus, this document takes away the novelty of claims 51-55.

Document D11 discloses the manufacture of fish feed with e.g., rosemary used as an antioxidant. A concentration of 0.05% may be used (p.6 I.23) Thus, this document takes away the novelty of claims 51-55.

V.2.3 Invention 3: based on lavender

Document D9 discloses the use of many compounds and ingredients, including lavender oils and extracts (§60), in in the feed of aquatic animals for the control of parasite and bacterial infections, such as in fish (§40). Thus, this document takes away the novelty of claims 72-75 and 77 (see also VIII.1). There appears to be no inventive step for the change of the mode administration from feed to water, or for a dose range in the feed. Thus, the subject-matter of claims 64-71 and 76 does not involve an inventive step.

Document D12 discloses that select essential oils are effective against Caligus disease in fish, such as salmonids. These essential oils may be used in fish feeds or as chemical immersion solutions. Lavender oil is mentioned as a suitable oil (§17). It follows that this document takes away the novelty of claims 64-66, 70-71, 72-75 and 77. There appears to be no inventive step for the selection of specific fish families, or for a dose range in the feed. Thus, the subject-matter of claims 67-69 and 76 does not involve an inventive step.

V.2.4 Invention 4: based on bog myrtle

Document D9 discloses the use of many compounds and ingredients, such as essential oils, in the control of parasite and bacterial infections of the fish. It cites limonene (§55), which is comprised in the essential oil of bog myrtle (see D14). Thus, in light of this document, a skilled person would search for a source of limonene and find it effective against bacterial infections of the fish. Alternatively, that person would know from D14 that limonene can be brought by bog myrtle. For these reasons, the subject-matter of claims 85-92 and 93-98 is considered to lack an inventive step in light of D9 or alternatively, D9 and D14.

V.2.5 Invention 5: based on isothiocyanates

No relevant prior art was found. Indeed, documents D15 and D16 disclose alternative pharmaceutical compounds. It follows that the subject-matter of claims 99-146, is considered to be new and to involve an inventive step (Art. 33 (2) and (3) PCT).

V.3 The most relevant passages of the above-cited documents are those mentioned in the International search report, to which the Reader is referred.

V.4 Industrial applicability

V.4.1 Claims 1-24, 30, 36-50, 56, 57-71, 77, 78-92, 98, 99-134, and 146 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) / 67.1(iv) PCT.

The subject-matter of all the other claims is considered to be susceptible of industrial application in the meaning of Art. 33 (4) PCT.

Re Item VIII

Certain observations on the international application

VIII.1 Claims 52-54, 73-75, and 94-96 are not clear (Art. 6 PCT), since their features are not features of the feed composition itself. Thus, said features were not taken into account for the assessment of novelty and inventive step.