PATENTS ACT 1977

IN THE MATTER OF
an application under Section 72(1)
by Vetrepharm Limited and Alpharma
for the revocation of Patent Number GB 2270261 B
in the name of Vericore Limited

DECISION

Introduction

1 On 16 March 1992 Peter Hand Animal Health Limited filed under the Patent Cooperation Treaty international patent application no. PCT/GB 92/00470, which was published as WO 92/16106. This international application claimed an earlier priority date of 18 March 1991 and designated the United Kingdom among other states. Subsequently, the international application entered the UK national phase as GB application no. 9319141.9 and on 14 December 1994 this GB application was granted as patent no. GB 2270261 B ("the patent") under the title "control of sea lice in seawater fish". On 2 June 1999 Vericore Limited ("the proprietor") became the registered proprietor of the patent.

2 An application under section 72(1) of the Patents Act 1977 ("the Act") for revocation of the patent was filed on 28 May 1999 by Vetrepharm Limited and Alpharma ("the applicants"). The grounds relied on by the applicants are set out in their statement but can be summarised as follows:

- the subject matter of the patent was known before the priority date of the patent;
- the subject matter of the patent would have been obvious at the priority date;
- insufficiency, that is that the patent does not disclose the invention clearly and completely enough for it to be performed across its entire breadth by a person skilled in the relevant art; and
- the patent relates to subject matter which was not disclosed in GB application no. 9319141.9.

Thirteen prior art documents (referenced D1 to D13) are cited by the applicants in support of their case.

3 The proprietor filed a counter-statement on 10 November 1999 denying that the patent is invalid, whether for the reasons relied on by the applicants or at all. There then followed the normal evidence rounds, with the applicants and the proprietor filing evidence-in-chief on 14 July 2000 and 12 February 2001, respectively, and the applicants filing their evidence-in-reply on 18 April 2001.

4 However, one matter was still outstanding at the time the applicants filed their evidence-in-reply. In a letter dated 29 March 2001 the applicants' patent agents sought clarification from the proprietor whether the proprietor intended to rely on commercial success as an "antidote" to obviousness. If this was to be the case, the applicants asked for a schedule giving a summary of all the expenditure relating to the advertising and promotion of a cypermethrin-based product, marketed under the registered trade mark "Excis", in Norway between 1993 and 1999. As I will explain below, the patent relates to such a product. On 14 June 2001, the proprietor filed a statutory declaration addressing this outstanding issue.

5 The matter duly came before me at a hearing at which Mr Richard Hacon, instructed by patent agents D Young & Co, appeared as Counsel for the applicants and Mr David Young QC and Mr Geoffrey Pritchard, instructed by patent agents J Y & G W Johnson, appeared as Counsel for the proprietor. At the hearing, I had the benefit of a skeleton argument from Mr Young and two from Mr Hacon.

6 As I have mentioned, the applicants in their original statement identified four grounds on which they sought revocation of the patent. However, at the hearing Mr Hacon informed me that the applicants' case now rested solely on the grounds of lack of novelty in claims 1 and 4 and lack of inventive step in all the claims. I do not therefore need to consider further the originally pleaded grounds of insufficiency and added subject matter.

Preliminary points

7 At the hearing it was necessary for me to give directions on two preliminary points concerning the second statutory declaration of one of the applicants' witnesses, Dr Tor Einar Horsberg, and the late-filed second statutory declaration of one of the proprietor's witnesses, Ms Joanne Hardwick.

Dr Horsberg's second statutory declaration

8 The evidence-in-reply filed by the applicants included a second statutory declaration from Dr Horsberg who had provided evidence-in-chief *inter alia* on the availability of one of the documents relied on by the applicants as to whether the subject matter of the patent was not only known but also obvious. At the hearing Mr Young submitted that Dr Horsberg's second statutory declaration should not be admitted because it introduced opinions held by Dr Horsberg as an expert and thus was not strictly in reply; in other words, Dr Horsberg had taken on the mantle of an expert witness in his evidence-in-reply. Mr Young went on to make the point that this increased the total number of expert witnesses relied on by the applicants to three, and in his view this was too many bearing in mind the limit placed by the High Court on the allowable number of experts. Mr Hacon responded by pointing out that Dr Horsberg was indeed an expert and that this had been acknowledged by one of the proprietor's own expert witnesses, Dr Hamish Rodger, in his evidence. Moreover, Mr Hacon noted that no Order had been made limiting the number of experts in this case. As for the proposition that Dr Horsberg's second statutory declaration was not strictly in reply, Mr Hacon drew my attention to cross-references in its paragraphs 12 to 18 to the earlier evidence of Dr Rodger and the proprietor's other expert witness, Mr Farrelly.

9 In considering the arguments put to me, I indicated that I did not attach great weight to the possibility that the applicants might be increasing the number of expert witnesses available

to them, in part because Dr Horsberg had already contributed to the applicants' evidence-in-chief. That said, I was not persuaded that paragraphs 2 to 9 of Dr Horsberg's second statutory declaration were in reply and at the hearing gave my decision to admit only paragraphs 1 and 10 to 19 of this statutory declaration.

Ms Hardwick's second statutory declaration

10 I have explained above that the evidence rounds were completed by 18 April 2001 with the exception of a second statutory declaration of 14 June 2001 by one of the proprietor's witnesses, Ms Hardwick. At the hearing I was concerned that the applicants might not have had sufficient time to consider this new evidence and in particular to file any evidence-in-reply to it. However, when I asked Mr Hacon whether he had any objection to the admission of this late-filed evidence, he replied that he had none. I therefore admitted the late-filed evidence of Ms Hardwick in full.

The technical field

11 Before turning to the subject matter of the patent, it may be helpful briefly to outline the technical field of these proceedings. It relates to salmon and other sea fish, and more especially to infestation with sea lice to which they are susceptible. Sea lice are ectoparasitic marine crustacea which eat the membrane, skin and blood of their host. There are two main types of louse relevant here: *Lepeophtheirus salmonis* and *Caligus elongatus*. Treatments for sea lice infestation do not differentiate between the two. On wild salmon only small numbers of sea lice are normally found, but in farming conditions where fish density is very high, infestation is a major problem. Heavy infestations cause stress among the fish, reduced feeding activity, and low weight gains. The consequences for the fish are highly unpleasant and may result in high mortality rates. Over the years, different treatments for sea lice infestation have been used, in particular the organophosphate dichlorvos. For various reasons which I shall come to, dichlorvos was not regarded as the last word, and alternative treatments were being sought.

12 Pyrethrum is an extract from Chrysanthemum flowers which contains a mixture of natural compounds including pyrethrins. Pyrethrum powder has been used for many years as an insecticide in domestic situations. Compounds having similar structures and properties to pyrethrins have been developed as insecticides. The use of pyrethrum and related synthetic compounds in treating sea lice infestation on salmon and other sea water fish goes to the heart of the present dispute.

The patent

13 The patent explains that it relates to the control of sea lice in seawater fish, particularly salmon. According to the "Background Art" section of the patent, it was known to use the organophosphate insecticide dichlorvos to treat salmon suffering from sea lice infestation. However, dichlorvos is generally only effective against mature sea lice and great care has to be taken with the dosage because it is fatal to fish at eight times its recommended dose for sea lice treatment. Moreover, there were indications that sea lice were developing resistance to this insecticide.

14 It was also said to be known to use pyrethroid pesticides, particularly cypermethrin and alphacypermethrin, to control pests in crops and against ectoparasites in cattle and sheep. For example, the patent refers to a statement in the Pesticide Manual that for cypermethrin the LD_{50} (96 hours) for brown trout is 2.0 – 2.8 microgram/litre. I should explain that "LD_{50} (96 hours)" is a measure of the lethal dose for 50% of the treated brown trout after exposure for 96 hours. The patent refers to further data on the toxicity of cypermethrin to fish which is published in "Environmental Health Criteria 82: Cypermethrin" by the World Health Organisation, Geneva 1989. This publication reports a LD_{50} (96 hours) of 2.0 - 2.4 microgram active ingredient/litre for Atlantic salmon weighing 5.3g.

15 The patent goes on to state:

> "Because of these figures it has been considered that cypermethrin is too toxic for use on fish."
>
> "However, we have found that pyrethroids, particularly cypermethrin and alphacypermethrin, can be administered to salmon and other seawater fish in a manner which is highly effective in the control of sea lice in the salmon and other fish while being much less toxic to the fish themselves than dichlorvos."

16 The patent contains fourteen claims, which read:

> "1. Use of a pyrethroid pesticide for the manufacture of a composition for the treatment of sea lice infestation in seawater fish in a sea water environment.
>
> 2. Use according to claim 1 wherein the pyrethroid pesticide is cypermethrin or alphacypermethrin.
>
> 3. Use according to claim 1 or 2 wherein the composition containing the pesticide is a composition to be administered orally.
>
> 4. Use according to any of claims 1 to 3 wherein the seawater fish is salmon.
>
> 5. Use according to claim 2 or any claim dependent thereon wherein the composition containing the cypermethrin or alphacypermethrin is to be administered orally at a dosage rate of 0.025 – 5.0 mg/kg of fish body weight.
>
> 6. Use of a pyrethroid pesticide in water for the manufacture of a treatment suspension for salmon suffering from sea lice infestation.
>
> 7. Use according to claim 6 wherein the pyrethroid pesticide is cypermethrin or alphacypermethrin.
>
> 8. Use according to claim 6 or 7 wherein the pyrethroid pesticide is administered in a range between 0.001 and 0.5 ppm by weight of pyrethroid pesticide to water.
>
> 9. A composition when used for controlling sea lice infestation in salmon which comprises a pyrethroid pesticide suspended in water.

10. A composition according to claim 9 wherein the pyrethroid pesticide is cypermethrin or alphacypermethrin.

11. A composition according to claim 9 or 10 when externally administered to salmon.

12. A food composition suitable for salmon, characterised in that in addition to food ingredients it contains a pyrethroid pesticide.

13. A food composition according to claim 12 characterised in that it contains cypermethrin or alphacypermethrin as the pyrethroid pesticide.

14. A food composition according to claim 12 or 13, characterised in that it contains the pyrethroid pesticide in an amount to provide a dosage of 0.025 – 0.5 mg pyrethroid per kg body weight of seafish.

17 Thus, there are four independent aspects to the invention as claimed. Claims 1 and 6 are in the form of what is commonly called the "Swiss-type" and are based on the use of a pyrethroid pesticide; claim 9 is to a composition comprising a pyrethroid pesticide when used for controlling sea lice infestation in salmon; and claim 12 is to a food composition containing a pyrethroid pesticide. According to the description on page 3 of the patent, the pyrethroid pesticide can be used in suspension or emulsified concentrate form or as a solid formulation (eg powder or granules) and it can be administered to the seawater fish in their feed or as a bath treatment.

18 The patent acknowledges that it is not fully understood why cypermethrin is not toxic to the salmon or other seawater fish when used according to the invention. It is suggested that the greater tolerance to cypermethrin may be due to the presence of seawater rather than freshwater. The patent mentions particular surprise that alphacypermethrin is highly effective when administered orally; it later suggests that the active ingredient when administered orally is taken up by the fish and passes through to the skin where the lice exist as topical ectoparasites.

19 The patent describes various experiments both on sea lice that have been isolated from their salmon hosts and on salmon infected with sea lice. In a first series of experiments, described under the heading "Example 1", solutions of cypermethrin and alphacypermethrin at concentrations ranging from 0.001 to 10 ppm were prepared and their acute toxicities to sea lice determined. A second series of experiments, identified as "Example 2", looked at the toxicity of cypermethrin and alphacypermethrin to male, female and pre-adult sea lice. Both compounds were found to have significant toxicity to all groups. A further Example, "Example 3", describes a series of trials to assess the toxicities of cypermethrin and alphacypermethrin to sea lice *in vivo*. In these trials salmon infected with sea lice were treated for an hour in water tanks with the active ingredients at concentrations of 0.01, 0.05 and 0.1 ppm. One fish died as a result of jumping out of its tank but this was the only one to die. On the other hand only one louse survived after 24 hours. In a similar trial where the concentration of cypermethrin and alphacypermethrin was generally reduced to 0.001, 0.005 and 0.01 ppm, again a fish died when it jumped out of its tank but this was the only fish casualty of the trial. As for the sea lice only a few

survivors were found in the 0.001 ppm treatment groups. In further trials, described as "Example 4", salmon were given three one hour treatments with cypermethrin and alphacypermethrin at 0.5 ppm at 24 hour intervals. In these trials a few fish did die as a result of the treatment and the others showed a marked reaction to it. Alphacypermethrin was found to be marginally more toxic to both salmon and lice than cypermethrin. Cypermethrin was found to be the most efficacious since the salmon could tolerate repeated doses at 100 times the dose rate required to remove all the lice from infected fish. A last series of experiments, identified as "Example 5", involved feeding salmon a medicated diet containing alphacypermethrin at dose rates of 0.025, 0.05, 0.1, 0.5 and 1.0 mg/kg for three consecutive days. These trials did not result in any fish mortalities and in the patent it is claimed that overall the efficacy of the compound was good. The patent also gives examples of five other pyrethroid pesticides tested as bath treatments at two different concentrations. The results given show that these other pesticides are also capable of killing sea lice.

The evidence and witnesses

20 The written evidence-in-chief filed by the applicants comprises statutory declarations with exhibits by Dr Tor Einar Horsberg, Professor Anders Goksøyr, Professor Jørgen Herman Vogt Stenersen and Jens Christian Holm. The applicants' written evidence-in-reply comprises second statutory declarations by Dr Horsberg, Professor Goksøyr and Professor Stenersen, with Professor Stenersen's second declaration being accompanied by further exhibits. I have already mentioned that I admitted only part of Dr Horsberg's second statutory declaration. At the hearing Mr Hacon introduced amendments to the first declarations of Professor Goksøyr and Professor Stenersen, and to the second declaration of Dr Horsberg. Dr Horsberg, Professor Goksøyr and Professor Stenersen were each cross-examined at the hearing.

21 Dr Horsberg and Tonje Høy, who I understand is his wife, are the authors of a thesis on "Chemotherapy of Sea Lice Infestations in Salmonids: Pharmacological, Toxicological and Therapeutic Properties of Established and Potential Agents". (I shall call this "the Horsberg thesis", or D1 as it is referenced in the applicants' prior art.) Dr Horsberg is currently an associate professor at the Norwegian School of Veterinary Science working within the Pharmacology and Toxicology Division. Although a Norwegian national it was clear to me during his cross-examination that he understood and spoke English well. I found Dr Horsberg a clear, consistent and convincing witness who was not only knowledgeable but also enthusiastic about the field of technology represented by the patent.

22 Professors Goksøyr and Stenersen were both presented by the applicants as expert witnesses and I was left in no doubt following their cross-examination that they are indeed experts in their fields. Professor Goksøyr is a molecular- and eco-toxicologist and has specialised in research into marine organism toxicology. Early in 1991 he was involved in a project financed by the former Norwegian Fisheries Research Council and Norsk Pyrethrum AS to study the use of pyrethrum as a pesticide for the treatment of sea lice infestation in salmon. Although not a native English speaker Professor Goksøyr spoke and understood English well. During his cross-examination I found him clear, consistent, credible and helpful. He was honest about the limits of his own knowledge, but stood his ground under pressure on matters within his knowledge. Professor Stenersen has been Professor in Biology at the Biological Institute at the University of Oslo since 1993 and has

devoted much of his career to the study of pesticides. When giving oral evidence Professor Stenersen explained that he once worked with a student on a project concerning sea lice. Professor Stenersen experienced some difficulty in communicating in English during cross-examination, but I am satisfied that this difficulty did not have a bearing on his eventual understanding of the questions put to him or to the answers he gave to them. Professor Stenersen was clearly eager to help the tribunal but I felt that this eagerness occasionally led him to speculate.

23 Mr Holm, who was not cross-examined, is currently principal scientist at the Institute of Marine Research at the Austevoll Aquaculture Research Station in Norway. It was at this Institute in 1989 and 1990 that he was involved in a project to evaluate pyrethrum for use as a pesticide for salmon lice. The applicants rely on various disclosures concerning this research.

24 The written evidence-in-chief filed by the proprietor comprises an affidavit with exhibits of Dr Hamish D Rodger, an expert report with exhibits by Mr Eamonn Farrelly, a statutory declaration with exhibits by Mr Julian Charles Braidwood, and two statutory declarations of Ms Joanne Hardwick with the second being accompanied by exhibits. Dr Rodger and Mr Farrelly were expert witnesses for the proprietor and were cross-examined at the hearing, as was Ms Hardwick.

25 Dr Rodger is an aquaculture veterinarian and as such has specialised in the health management, diagnosis, treatment and prevention of disease in aquatic animal species. From 1985 he has worked on sea lice control and in particular on the chemotherapy of sea lice. Mr Farrelly is a ecotoxicologist and has particular expertise in testing the effects of pyrethroid insecticides on fish and aquatic invertebrates. As with the applicants' expert witnesses, both Dr Rodger and Mr Farrelly are clearly experts in their fields and the oral evidence they gave was on the whole helpful. Under cross-examination, Dr Rodger generally seemed to me a fair and careful witness. However, and as Mr Hacon observed in his closing statement, it appeared to me that at times Mr Farrelly was concerned not to say anything that might undermine the proprietor's position in this case. For example, when asked by Mr Hacon for his take on the term "pyrethroid" as used in the article at D7 in the prior art bundle, Mr Farrelly was very reluctant to give a straight answer, so much so that I felt I had to intervene to have the answer given. This gives me less confidence in Mr Farrelly as an expert witness in those instances where his opinion differs from that of the other experts.

26 Ms Hardwick was global Marketing Manager for Peter Hand Animal Health Limited at the priority date of the patent and has been employed ever since by the various companies which have owned the patent. Over the years she has been involved continuously with the development and subsequent marketing of the product "Excis" (RTM), which is a cypermethrin-based product protected by the patent. During her cross-examination I thought that Ms Hardwick was a robust and precise witness who did her best to provide accurate information about the market for sea lice treatments and in particular Excis's place in that market.

27 Mr Braidwood, who was not cross-examined, is one of the inventors of the invention claimed in the patent and until November 2000 was employed by the various companies which have successively owned the patent. Despite this technical background, Mr

Braidwood's written evidence only addressed the date when the Horsberg thesis was first available for public inspection at certain libraries in Norway.

The law

28 The grounds on which a patent may be revoked are set out in section 72 of the Act. The applicants initially sought revocation broadly under sub-section (1) but at the hearing they restricted the grounds to those specified in sub-section (1)(a), which reads:

> "**72**.– (1) Subject to the following provisions of this Act, the court or the comptroller may on the application of any person by order revoke a patent for an invention on (but only on) any of the following grounds, that is to say-
>
> (a) the invention is not a patentable invention;"

29 What constitutes a patentable invention is defined in section 1 of the Act and in particular, for present purposes, in sub-section (1), which requires that a patent may be granted only for an invention which (a) is new and (b) involves an inventive step. The criteria of novelty and inventive step are defined in sections 2 and 3 respectively, the relevant provisions of which are:

> "**2.**- (1) An invention shall be taken to be new if it does not form part of the state of the art.
>
> (2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way."
>
> "**3.** An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above)."

30 What can be regarded as forming "part of the state of the art", and so be used to show that an invention is not new or lacks an inventive step, was explained in *PLG Research Ltd. and Another v. Ardon International Ltd. and Others* [1993] FSR 197, to which I was referred by Mr Hacon. To quote Aldous J at page 226:

> "Thus to form part of the state of the art, the information given by the use must have been made available to at least one member of the public who was free in law and equity to use it."

31 Although *PLG v. Ardon* was concerned with prior use, the principle stated by Aldous J applies equally to information contained in a document. Thus, to form part of the state of the art, a document must have been made available in circumstances such that at least one member of the public was free to use the information contained in it. It is established law that there is no additional requirement that someone should actually have inspected the document or even that anyone should be aware that the document was available for public

inspection. On this latter point Mr Hacon drew my attention to the Decision of the EPO Board of Appeal T381/87 *Research Corporation* [1989] EPOR 138 at page 144:

> "It is not necessary as a matter of law that any members of the public would have been aware that the document was available upon request on that day, whether by means of an index in the Library or otherwise. It is sufficient if the document was *in fact* available to the public on that day, whether or not any member of the public actually knew it was available, and whether or not any member of the public actually asked to see it."

32 Considering now the question of novelty, it is also established law that for anticipation under section 2(2) the earlier published information should contain an enabling disclosure. On this point I was directed by both Mr Hacon and Mr Young to *Evans Medical Ltd's Patent* [1998] RPC 517, and in particular to Laddie J's statement on page 550 that:

> "If an inventor through clever foresight or lucky guess work describes something which works and how to do it, his disclosure is enabling. It is *nihil ad rem* that he never carried out the experiments themselves or faked the results. The more complex the area of technology, the less likely it is that the inventor will be able to predict the results of experiments he never carried out or that he will strike lucky, but what is important is what the document teaches, not how the contents got there."

33 I would also take from pages 560 and 561 of *Evans Medical* that the tests for enablement and obviousness differ: a disclosure in a piece of prior art might render a step obvious (for example if a reader might think that there is sufficient prospect of success to warrant trying it out) even though it is not in itself enabling.

34 That leads me on to review the case law on the approach to be taken when considering whether a claimed invention involves an inventive step in the face of prior disclosure. Mr Hacon referred me to the test laid down by the Court of Appeal in *Windsurfing International Inc. v. Tabur Marine (Great Britain) Ltd.* [1985] RPC 59. Although this test is well established, I consider it useful to set it out here. Thus, *Windsurfer* requires four steps to be taken when answering the question on obviousness, namely:

> (i) to identify the inventive concept embodied in the patent in suit;
>
> (ii) to impute to a normally skilled but unimaginative addressee what was common general knowledge in the art at the priority date;
>
> (iii) to identify the differences if any between the matter cited and the alleged invention; and
>
> (iv) to decide whether those differences, viewed without any knowledge of the alleged invention, constituted steps which would have been obvious to the skilled man or whether they required any degree of invention.

35 Section 125(1) of the Act indicates what is understood to be the "invention" protected by the patent. It explains in effect that an invention for which a patent has been granted shall be taken to be that specified in the claims of the patent specification, as interpreted by the

description and any drawings. Mr Young directed me to *Improver Corporation and Others v. Remington Consumer Products Limited and Others* [1990] FSR 181 at page 189 for the law relating to construction. In *Improver* Hoffmann J (as he then was) formulated a series of three questions to be answered when a feature embodied in an alleged infringement, which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim, was nevertheless within its language as properly interpreted. These questions are:

> (i) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -
>
> (ii) Would this have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes -
>
> (iii) Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

36 What constitutes “common general knowledge" for the second *Windsurfer* step has been considered in a number of cases. For example, it is addressed in *The General Tire & Rubber Company v. The Firestone Tyre and Rubber Company Limited and Others* [1972] RPC 457, to which I was referred by Mr Young. In this Court of Appeal judgment Sachs LJ states at page 482:

> "The *common general* knowledge imputed to such an [skilled] addressee must, of course, be carefully distinguished from what in patent law is regarded as *public* knowledge."

37 Mr Young also directed my attention to *Beloit Technologies Inc. v. Valmet Paper Machinery Inc.* [1997] RPC 489 at pages 494 and 495 in which the Court of Appeal considered the question of common general knowledge and approved what was said by Luxmoore J in *British Acoustic Films* 53 RPC 221 although with some reservation over Luxmoore J's words "accepted without question". In *British Acoustic Films* it was said by Luxmoore J as regards scientific papers generally:

> "In my judgment it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art."

A little later, distinguishing between what has been written and what has been used, Luxmoore J said:

> "It is certainly difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art."

Mr Young's conclusion was that the differentiation between what is known and what is common general knowledge is a matter for the tribunal not any witness to determine, and that something widely known or widely read but never applied is unlikely to meet the test.

38 To apply the second *Windsurfer* step it is also necessary to identify the characteristics of the person skilled in the art. On this point Mr Hacon took me to *Pfizer's Patent* [2001] FSR 201 at paragraph 62 where Laddie J states:

> "The question of obviousness has to be assessed through the eyes of the skilled but non-inventive man in the art. This is not a real person. He is a legal creation. He is supposed to offer an objective test of whether a particular development can be protected by a patent. He is deemed to have looked at and read publicly available documents and to know of public uses in the prior art. He understands all languages and dialects. He never misses the obvious nor stumbles on the inventive. He has no private idiosyncratic preferences or dislikes. He never thinks laterally. He differs from all real people in one or more of these characteristics. A real worker in the field may never look at a piece of prior art - for example he may never look at the contents of a particular public library - or he may be put off because it is in a language he does not know. But the notional addressee is taken to have done so."

39 As confirmed by Laddie J in *Pfizer* at paragraph 67 it has been accepted law for many years that in appropriate cases the addressee for the purpose of testing obviousness can be a team made up of notional skilled but uninventive members from different disciplines.

40 The fourth and final *Windsurfer* step requires an assessment of what if anything would have been obvious to the skilled person. On this point Mr Hacon reminded me that it has long been the law that an alleged invention is obvious where the skilled person would have thought that it was obvious to try the step said to constitute the invention with a reasonable expectation of success. This is still good law as held by Laddie J in *Pfizer* at paragraph 106:

> "The question is, therefore, whether it would be obvious to try to use a cGMP PDE inhibitor in oral treatment or were the risks of failing so great as to deter the notional skilled worker before he set off down that path. Whether something is obvious to try depends to a large extent on balancing the expected rewards if there is success against the size of the risk of failure."

41 Mr Hacon argued that when considering whether something is obvious to try, one must see whether there was commercial demand for a solution to the problem. If there is the demand, the person skilled in the art is going to be much more willing to try things out. In his submission to me, Mr Young opined that a test where the risk of failure is weighed against commercial demand is not the right test. Mr Young emphasised that the correct test has to be a reasonable expectation of success, as established in *Genentech Inc's Patent* [1989] RPC 147, not the mere hope of succeeding. Neither is the test whether it would have appeared commercially worthwhile to exploit the invention, as established in *Hallen*

Co. and Anr. v. Brabantia (UK) Ltd. [1991] RPC 195. I do not see any inconsistency between what Laddie J said in *Pfizer* and what the Court of Appeal said in *Genentech* and *Hallen v Brabantia*. From *Genentech* it is clear that the basic test is whether the person skilled in the art would assess the likelihood of success as sufficient to warrant actual trial, without postulating prior certainty of success. From *Hallen v Brabantia* it is also clear that the test for inventive step is not whether an advance is *commercially* obvious but whether it is *technically* obvious. However, as indicated by Laddie J in *Pfizer* in the real world the person skilled in the art is going to have a greater incentive to try things the more the expected rewards outweigh the size of the risk of failure.

42 The commercial success of a patented invention is sometimes used to indicate inventiveness in circumstances where there has been a long-felt want. In this regard, Mr Hacon directed me once again to *Pfizer* and Laddie J's statement at page 244 that:

> "Even doing what is obvious can be commercially successful. Commercial success comes into its own as a secondary indication of inventiveness where both the relevant prior art has been available and the need for a solution to a known problem has been sought for a long time. Failure to make the step which is covered by the patent in those circumstances may be some indication that it is not as obvious as it might first appear. That has no application here where the gap between the prior art and the priority date is so very short."

The cited documents

43 It is convenient at this point to list, by the "D" references they ascribed to them, the prior art documents which the applicants have cited in support of their case. They are:

D1 Thesis "Chemotherapy of Sea Lice Infestations in Salmonids: Pharmacological, Toxicological and Therapeutic Properties of Established and Potential Agents" by Hoy and Horsberg (This is what I have called "the Horsberg thesis".)

D2 Annual Meeting Seminar on Fish Health: Jakobsen and Holm "New Pesticide for Salmon Lice" - Promising trials using Pyrethrum

D3 Palmer Et Al; Bull Eur Assoc Fish Pathpol 7: 47-53 " Preliminary Trials on the Efficacy of Ivermectin against Parasitic Copepods of Atlantic Salmon"

D4 Hill IR (1989) Pestic SCI 27 " Aquatic Organisms and Pyrethroids"

D5 Elliot M "The Pyrethroids: Early Discovery. Recent Advances and the Future" Pestic SCI (1989) 27: 337-351

D6 Crossland No (1982) "Aquatic Toxicology of Cypermethrin II."

D7 Fish Farming International, 20th June 1990, " Search for New Ways to Curb Sea Lice" and "Work in Norway"

D8 Official Journal of the European Communities No C90/15, 9th April 1990, Question No. 552/89

D9 Irish Salmon Growers Association Annual Conference 12013 October 1990, " Alternative Chemical Treatments to Sea Lice" Boxaspen, Holm and Jakobsen

D10 Australian Patent Application 58755/90

D11 Kumaragau (1981) Water Research 15: 503-505 " Lethal Toxicity of Permethrin to Rainbow Trout in relation to Body Weight and Temperature"

D12 Edwards (1987) Xenobiotica 17(10) " the Toxicity and Metabolism of the Pyrethroids cis- and Trans-Cypermethrin in Rainbow Trout."

D13 Deltamethrin Monograph by Roussel-Uclaf 1982

44 In the event, at the hearing the applicants relied chiefly on five of these citations. It is convenient if I summarise the relevant disclosure in those five documents now.

The Horsberg thesis (D1)

45 The Horsberg thesis is entitled "Chemotherapy of Sea Lice Infestations in Salmonids: Pharmacological, Toxicological and Therapeutic Properties of Established and Potential Agents". The thesis describes the therapeutic efficacy of established and potential treatments for sea lice infestations. Thus, for example, it describes the use of dichlorvos as a delousing agent in salmon, a treatment which is acknowledged as background art in the patent. Of particular relevance is a discussion towards the end of the thesis under a sub-heading "Pyrethroids" of then current studies on the potential of pyrethroid insecticides as delousing agents in salmon. The thesis reports that preliminary clinical trials with pyrethrum administered on the water surface using an oil as a vehicle have demonstrated a certain clinical effect on sea lice. It goes on to explain that pyrethrum is an extract of the plant *Chrysanthemum cinerariaefolium* and contains various pyrethrins with insecticidal properties. The thesis notes that the mixture of insecticidal agents which make up pyrethrum is extremely toxic to fish but that high toxicity does not necessarily exclude a substance from therapeutic use. This is because the margin between the toxic dose for the parasite and the toxic dose for the fish is an important factor. Nevertheless, this margin remained to be determined for pyrethrum.

46 The thesis notes that pyrethrins are unstable compounds which are rapidly decomposed by light and exposure to air. As a consequence various chemicals, such as antioxidants, must be added to obtain stable formulations of pyrethrum. Moreover, an enzyme inhibitor, piperonyl butoxide, is added to enhance the insecticidal activity by reducing the parasite's ability to metabolise, and thereby, detoxify, the different pyrethrins. The thesis recognises that synthetic derivatives of natural pyrethrins had found use as insecticidal agents because the natural compounds are unstable and need added chemicals. In view of the better stability of synthetic pyrethroids compared to the natural pyrethrins and the fact that the synthetic compounds are equally or more potent pesticides, the authors suggest that it seemed probable that in the future synthetic pyrethroids will be of more interest than pyrethrum as possible delousing agents.

The Jakobsen and Holm paper (D2)

47 This is, in translation, a paper by Per Jakobsen and Jens Holm ("the Jakobsen and Holm paper"), which was published in the January 1990 edition of *Norsk Fiskeoppdrett*, a Norwegian aquaculture magazine. In his written evidence Mr Holm states that this paper represents a presentation given by Jakobsen and him at the Annual Meeting Seminar on Fish Health at the Scandic Hotel, Kokstad on 16 January 1990. The paper describes a trial aimed at delousing salmon, which involved allowing the salmon to hop through a layer of oil containing pyrethrum with added piperonyl butoxide. This mode of exposing the salmon to the pyrethrum is said in the paper to overcome the problem encountered in introductory tests using pyrethrum emulsified in water, which resulted in the death of the salmon. The paper reports the trial as having had obvious effects in reducing the number of lice on infected salmon and Holm and Jakobsen believed that they had proved that pyrethrum was a very promising candidate as a pesticide for salmon lice.

The Boxaspen paper (D9)

48 This represents a development from the previous document (D2) and is the text of a presentation given by Messrs Holm and Jakobsen with Ms Karin Boxaspen at the Irish Salmon Growers' Association Annual Conference and Trade Exhibition in Galway on 13 October 1990 ("The Boxaspen paper"). The text of the presentation describes the work done at the Austevoll Aquaculture Research Station in Norway on the use of pyrethrum as an alternative chemical treatment for sea lice. It mentions that the first experiment using a pyrethrum emulsion led to the rediscovery that pyrethrum is poisonous to fish and that it was not until autumn 1989 that a new administration principle was used for the first time. This principle is essentially as described in the Jakobsen and Holm paper. The Boxaspen paper describes how the earlier experiment of Jakobsen and Holm was repeated in May 1990 but with oil layers of greater thickness. Unlike the earlier Jakobsen and Holm experiment, the May 1990 experiment gave no significant difference in the number of lice before and after treatment apart from the one experiment (called the "four times standard" experiment) where the oily layer was four times thicker than the layer used by Jakobsen and Holm. This failure was attributed in part to the breakdown of the active ingredients in pyrethrum by sunlight. The paper describes further experiments where the salmon were dipped through an oil layer containing pyrethrum to simulate the salmon jumping through the oily layer. This experiment resulted in a 34% reduction in sea lice for two dips and a decrease of 88% for six dips . The paper describes another experiment in which salmon were quickly bathed in a small basin containing pyrethrum. This experiment gave the best result with a 89% reduction in sea lice. The overall conclusion given in the paper is that pyrethrum had shown itself to be an effective delousing agent but the method of applying the pyrethrum was not optimal.

Fish Farming International (D7)

49 This citation is the edition of Fish Farming International ("Fish Farming International") which was published on 20 June 1990, and more particularly two articles which appeared in that edition under the headlines "Work in Norway" and "Search for new ways to curb sea lice". The "Work in Norway" article reports trials involving the use of a natural insecticide, pyrethrin, to control sea lice infestation in farmed salmon. The other article reports various lines of research on curbing sea lice. One of the lines of research mentioned is a preliminary study by Stirling University on the use of a pyrethroid.

Written Answer to a Question to the EC Commission (D8)

50 A written question to the EC Commission seeks information on research into alternatives to the sea lice pesticide Nuvan (RTM). In its answer which was given on 13 December 1989 ("the Written Answer") the Commission referred to the evaluation of a pyrethroid at Stirling University.

Date on which the Horsberg thesis (D1) was made available to the public

51 The proprietor admitted that all of the documents, apart from one, relied on by the applicants were available to the public prior to the priority date of the patent, that is prior to 18 March 1991. The one exception was the Horsberg thesis (D1), which the proprietor maintained was not made available to the public until 20 March 1991. So before I consider the matters of novelty and inventive step based on this document, it is necessary to decide when it was made available to the public. Dr Horsberg sets out the events leading to the publication of his thesis in his written evidence, and he was cross-examined on this matter in some depth by Mr Young.

52 Dr Horsberg states in his first declaration and also explained under cross-examination that work on the thesis began in 1986 and that it was written up by the middle of January 1991. The thesis was then printed and Dr Horsberg received printed copies on 27 February 1991. The same day he delivered twenty copies of the printed thesis by hand to the Study Section of the Norwegian School of Veterinary Science ("NVH"), which at that time was called the Norwegian College of Veterinary Medicine. It was the job of the Study Section there to forward all necessary forms and papers, including the thesis, to the evaluation committee and certain libraries. Dr Horsberg gave evidence that the Study Section retained some copies and sent others to the external examiners, the National Library of Norway and to NVH's own library. A letter exhibited as TEH5 to Dr Horsberg's first statutory declaration indicates that the external examiners were sent their copies on 4 March 1991, at least to the extent that it carries the manuscript which in English translates to “handled 04.03.91". Dr Horsberg explained that the Study Section was open to the public and on this basis he believes that once the thesis had been delivered there anyone could have seen it. In his written evidence Dr Horsberg also states that on 27 February 1991 he supplied copies of the thesis to his supervisor and various other employees of NVH. Dr Horsberg states that he gave copies to his colleagues who had requested them without any express or implied restrictions on the use of the thesis.

53 For the proprietor, Mr Braidwood in his statutory declaration states that he contacted the National Library of Norway and the Library of the Norwegian College of Veterinary Medicine in March 1998 to enquire when copies of the Horsberg thesis were first available for public inspection. Exhibited to Mr Braidwood's statutory declaration are the responses he received from both these Libraries. A facsimile message from the National Library of Norway states that the thesis was publicly available there on 19 April 1991. A computer printout from the Norwegian College of Veterinary Medicine is said to indicate that six copies of the thesis were catalogued and made available to the public there on 20 March 1991. Under examination-in-chief, Dr Horsberg expressed his view that this probably meant they were catalogued by the librarian at that time point, not necessarily that they arrived then; they probably arrived earlier. He explained that the normal procedure would

be that the librarians would receive the copies and put them on the shelf until they had time to catalogue them.

54 When cross-examining Dr Horsberg, Mr Young asked what he knew about the public availability of the thesis in both the National Library of Norway and NVH's own library. Dr Horsberg replied that it was likely that copies of the thesis would have been despatched by NVH's Study Section to both these libraries on the same day as copies were sent to the external examiners, namely on 4 March 1991, but he admitted that he did not know for sure because he had no record on that point. Mr Horsberg's belief in the efficiency of the Norwegian postal service was such that he thought that the libraries would have received the thesis at most a few days later and then put it on their shelves before it had been catalogued. While on the shelves it could have been picked up by anyone visiting either library. This view was based on his own experience of seeing other uncatalogued theses on the shelves of the libraries.

55 I have carefully considered the evidence of Dr Horsberg and Mr Braidwood on this matter. While I do not believe Dr Horsberg was seeking to mislead me, it seems to me that for his version to be correct depends on a number of events, namely that:

- the thesis was actually sent out from the Study Section on 4 March 1991;
- the postal service was prompt in delivering it to the libraries;
- it received prompt placement in a public location on receipt;

and that, not least,

- the documents supplied by the libraries to Mr Braidwood and put in evidence by him are somehow wrong.

I therefore need to consider whether I prefer on the one hand the (possibly optimistic) speculation by Dr Horsberg, albeit based on frequent visits to and knowledge of the libraries or, on the other, documentary evidence from the two libraries exhibited by Dr Braidwood. On the balance of probabilities I am not persuaded that the Horsberg thesis was made available to the public in either the National Library of Norway and NVH's own library before 18 March 1991, which is the priority date of the patent. Without corroboration to support Dr Horsberg's belief that the thesis was sent by NVH's Study Section to these libraries on 4 March 1991 and that it was received by them just a few days later, I cannot conclude that this is what actually happened. Similarly, I am not persuaded that the thesis was available for public inspection in NVH's Study Section; as before, Dr Horsberg’s evidence on this point is speculative, albeit well meant.

56 However, I have Dr Horsberg’s unrebutted testimony that he supplied copies of the thesis to his colleagues on 27 February 1991 without any implied or expressed condition of confidentiality. In his submissions in reply, Mr Hacon emphasised the point that this evidence was effectively unchallenged. Mr Young said this was not so, and urged me to read the relevant part of the transcript especially carefully. Having done so, I note that Mr Young in cross-examining Dr Horsberg asked about the availability of the thesis to colleagues and suggested it may only have been to people within the department.

However, he did not press the point to any conclusion on the terms of the release to colleagues before moving on. What was clear from this part of Dr Horsberg's cross-examination was his obvious relish in the events of 27 February 1991, which he described as a special day for him. In particular he remembered the requests he received from other scientists in his department, which consisted of around 30 people, for copies of the thesis. The flavour of his responses under cross-examination was wholly consistent with his statutory declaration in which he says there was no confidentiality restriction attached to the release of his thesis to colleagues. This it seems to me meets the condition expressed in *PLG v. Ardon* that he made the thesis available to at least one member of the public who was free in law and equity to use it. I therefore conclude that the Horsberg thesis (D1) forms part of the state of the art relative to the patent and so is a document that I should take into account when considering the novelty and inventive step of the invention claimed in the patent.

The skilled person

57 A crucial question is: who is the skilled person in the context of the present invention? Its correct answering is essential to claim construction, novelty and inventive step considerations. Mr Hacon and Mr Young had different ideas on this matter. Mr Young dealt with it at length and it was one of the main themes in his cross-examination of the applicants' witnesses. He attempted to draw a distinction between, as he put it, those whose interest was the academic side of fish and those on the more practical side. Mr Young sought to persuade me that the primary skilled person in the art relevant to these proceedings was the fish health specialist, such as the proprietor's witness, Dr Rodger. Mr Young also accepted that Dr Horsberg and Messrs Jakobsen and Holm were persons skilled in the relevant art since as fish health specialists they were the sort of people who would have had an interest in facing problems and coming up with new treatments to combat sea lice. According to Mr Young a secondary addressee was a marine toxicologist or an ecotoxicologist, such as Professor Goksøyr and Mr Farrelly, who would be called on to advise on the environmental impact of pesticides. Professor Stenersen's expertise was he felt in the academic side of pesticide function and not at the practical level which we are considering here.

58 When addressing me on this question of the person or team skilled in the art, Mr Hacon's starting point was the focus in the patent on the toxic effect of pyrethroids and in particular the differential toxic effect of pyrethroids on sea lice and fish. Thus, in his opinion, as a matter of common sense, the patent was addressed to either a toxicologist who is interested in treating fish or, alternatively, it was addressed to a fish health expert, essentially a vet, who is interested in toxic substances for use in treating an infestation of sea lice. In other words the patent was addressed to a person with an overlapping expertise in toxicology and fish health. In terms of a team, the team could comprise a toxicologist and a fish health expert who did not have this overlapping expertise.

59 On this matter I find the position taken by Mr Hacon more persuasive than that of Mr Young. In particular it seems essential to me that the skilled person or team should possess the skills of both a fish health expert and a toxicologist. In view of the knowledge of both fields demonstrated by Dr Horsberg during his cross-examination I have no hesitation in agreeing with Mr Young, albeit on a different basis, that Dr Horsberg could be considered as someone skilled in the art of the patent. Similarly on the basis of their published work

on the treatment of sea lice infestations in salmon I can accept that Messrs Jakobsen and Holm are skilled in the relevant art. However, I have more difficulty agreeing with Mr Young that Dr Rodger falls into the same camp. On this point I was particularly struck by Dr Rodger's statement during cross-examination that he had no more than a passing knowledge and interest in pyrethroid pesticides. More generally Dr Rodger admitted that as an aquaculture veterinarian he could not speak for toxicologists. As a toxicologist Professor Stenersen is clearly someone with a wealth of knowledge on pesticides and their mode of action but in my view lacks in his own right the specific background in fish health required of the primary skilled person in this case. As for the other expert witnesses, I agree with Mr Young that Mr Farrelly would be a secondary addressee and I would put Professor Goksøyr into the same category.

60 I should make clear that in giving this assessment of the witnesses' expertise, I am doing so in the sense of linking it to the subject-matter of the patent. I readily accept all are experts in their respective fields. I should also make clear that I fully appreciate that in considering the skilled addressee of the patent for the purposes of claim construction, novelty and inventive step, it is the notional skilled addressee I need to have in mind rather than any actual individual.

Construction of the claims

61 As I have mentioned above, claim 1 is of the so-called "Swiss-type". Mr Young explained that the claim was in this form because medical treatments using pyrethroids were known and a "Swiss-type" claim allowed protection based on a second medical use for these compounds. However, neither Mr Hacon nor Mr Young addressed me in any detail on the specific issue of the interpretation of novelty of Swiss-type claims as a class. The only dispute between the parties on the construction of claim 1 and the other claims was over the meaning of "pyrethroid", more particularly on whether at the relevant date it was restricted to synthetic compounds or whether it also embraced naturally occurring pyrethrins. I will therefore restrict my consideration to this one matter when considering how the claims should be construed.

62 In their submissions to me on how I should construe the word "pyrethroid", Mr Young and Mr Hacon agreed that I should do so in the context of the patent. In his submissions Mr Young pointed out that there is no mention of "natural pyrethroids" or "pyrethrum" in the patent, and that the only pyrethroids it does mention are synthetic ones, in particular cypermethrin and alphacypermethrin, and other synthetic pyrethroids which are listed at the end of the description. I should therefore construe "pyrethroid" narrowly as embracing only synthetic pyrethroids and excluding natural pyrethrum. Mr Hacon on the other hand took the view that the patent does not indicate whether the word "pyrethroid" should be taken to include or exclude natural pyrethroids and so it was necessary to form a view on the balance of probabilities whether the skilled person would have considered the patent to cover only synthetic pyrethroids, or both synthetic and natural pyrethroids. Mr Hacon went on to suggest that the way forward was to take evidence from those skilled in the art and to look at relevant documentary evidence.

63 While I accept that I must construe the term "pyrethroid" in the context of the patent, the absence of intrinsic explicit assistance in the patent specification as to the meaning of the term means that it is appropriate that I should consider the extrinsic evidence that is

available as to the meaning that the skilled man would have attributed to the term “pyrethroid”. Of course I am not looking to determine what would be understood by the word today, rather I must consider what was understood by the word at the priority date of the application just over a decade ago.

64 There has been a considerable amount of evidence, both written and oral, placed before me on this matter and I shall begin by considering the evidence of the witnesses expert in the field. The proprietor's and the applicants' expert witnesses were not unanimous on the meaning of "pyrethroid" as it would have been understood by the skilled man in the field some ten years ago.

65 For the proprietor, Dr Rodger states in his written evidence that a fish health specialist, which I take to include an aquaculture veterinarian such as himself, would have no more than a passing knowledge and interest in pyrethroid pesticides. In his oral evidence Dr Rodger confirmed that he was not an expert on pyrethroids. Thus, I do not consider that I am helped very much by Dr Rodger's written evidence that a fish health specialist would refer to a standard reference and conclude that pyrethroids are strictly limited to synthetic compounds. On the other hand Mr Farrelly, as an experienced ecotoxicologist, states in his written evidence that he has no doubt that the term "pyrethroid" properly refers only to synthetic compounds. Under cross-examination Mr Farrelly held fast to his opinion but I did not find him entirely convincing. When asked by Mr Hacon to comment on text by a Dr Elliott, Mr Farrelly seemed to be saying that Dr Elliott was careful in his choice of words but had nonetheless used the term “pyrethroid” inaccurately. Moreover, in my view he did not give a satisfactory response when asked by Mr Hacon to comment on various pieces of scientific literature which *prima facie* indicated that at least a significant part of the scientific community used the term "pyrethroid" to represent both synthetic and natural compounds. Indeed it was primarily on this aspect I felt that Mr Farrelly's answers were evasive and the manner in which he gave them seriously risked creating the impression that he was protecting the proprietor's position.

66 For the applicants, Professor Goksøyr, who like Mr Farrelly is an ecotoxicologist, states in his written evidence that if he had read the patent in 1991 he would have assumed that it was not intended to cover pyrethrum because it does not refer at all to pyrethrum. It may be a matter of expression, but with respect to the Professor, this does not really help me: it is for the tribunal to construe the patent and what I look for from the expert witnesses is their expert opinions on what the skilled man would have understood "pyrethroid" to mean. In his written evidence Professor Goksøyr states that he only uses the word "pyrethroid" to describe the synthetic compound, but he adds that he is aware that many other people use the word to describe both the synthetic and the natural, and concludes his second declaration by saying that most people would agree that the broader definition was commonly used. Professor Stenersen, who has been involved with the study of pesticides for much of his career, states in his first statutory declaration that in 1991 he would have used, and still uses, the term “pyrethroid” to refer to both synthetic and natural pyrethroids, and that he believes that his use of the term is consistent with the general use of the term among toxicologists both now and in 1991. Under cross-examination, Professor Stenersen confirmed that generally he regarded the word "pyrethroid" to cover both the natural and synthetic compounds. Finally, there is the evidence of Dr Horsberg who struck me when he gave his oral evidence as someone who was knowledgeable about "pyrethroids" in 1991. In his first statutory declaration he states that the term "pyrethroid" was used in his thesis

(which is contemporaneous with the patent application) to refer generically both to naturally occurring pyrethrins and to their synthetic analogues. He also states that in his experience, pyrethrins and synthetic pyrethroids are frequently presented under the heading "Pyrethroids".

67 Thus, Mr Farrelly and Professor Goksøyr took a narrow view of what they understood by the word "pyrethroid", although Professor Goksøyr admitted knowledge of wider usage. Professor Stenersen and Dr Horsberg considered that the word covered natural as well as synthetic compounds. As indicated above, I can attach no weight to the views of Mr Rodger on this matter in view of his admitted lack of first hand knowledge of pyrethroids. Furthermore, I consider that I must treat Mr Farrelly's opinion with some caution in view of the manner in which he presented it.

68 Bearing in mind the lack of consensus amongst the experts, I will now turn to various scientific papers or extracts from such papers, which were referred to by Mr Young and Mr Hacon during the hearing and which illustrate how the word "pyrethroid" is used by the scientific community. Mr Hacon suggested that standard texts are in any case the best guides as they are very likely to reflect the standard usage, which is what the skilled man would adopt. All of the following papers were either cited by the applicants or exhibited by the witnesses.

(i) *Chemotherapy of Sea Lice Infestations in Salmonids: Pharmacological, Toxicological and Therapeutic Properties of Established and Potential Agents*

This is of course the Horsberg thesis (D1) and it includes a section headed "Pyrethroids". The opening sentence of this section states:

"Among the substances currently being studied for their potential as delousing agents in salmon are the pyrethroid insecticides."

The thesis goes on to refer to the study involving pyrethrum. It is perhaps not surprising that the word “pyrethroid” was used here to embrace the natural material in view of Dr Horsberg's personal view on this matter.

(ii) *Ann. Rev. Entomol. 1978. 23:443-69, "The Future of Pyrethroids in Insect Control" (Elliott, Janes and Potter)*

Mr Hacon referred specifically to the opening paragraph of this item on page 443 which reads:

"The more stable synthetic pyrethroids, the main subject of this review, are based on the earlier natural and synthetic pyrethroids, but differ so markedly from them in properties and activity as to constitute a new class of insecticides."

He then moved on to page 444 where there is a statement that:

"The problem of defining the term "pyrethroid" is discussed in a complementary review (51), which emphasizes structure-activity relationships; although both the natural compounds and their synthetic analogues produce generally similar symptoms of poisoning

in insects, the mode of action is not known in sufficient detail to serve as a basis for definition."

He then went to page 449 where there is a table listing "natural pyrethroids" and specific synthetic pyrethroids under the common heading "Pyrethroids".

In relation to this article, Mr Young said that it showed a problem with the terminology even in 1978.

(iii) *Deltamethrin Monograph (Roussel-Uclaf, 1982)*

This item comprises merely a title page, a page showing the date and a contents page. Mr Hacon's interest was in the list of contents for Chapter 1 and in particular to a reference to:

"4) A special class of insecticides : the pyrethroids .....
a/ Natural pyrethrins .....
b/ The allethrins …….....
c/ Etc .....".

(iv) *Kjemiske plantevernmidler (Yrkeslitteratur as, 1988)*

This item, which was again referred to by Mr Hacon, is a Norwegian document written by Professor Stenersen, which when translated relates to "Chemical pesticides". Only an extract headed "Pyrethroid", a title page and a page establishing the date are exhibited. The extract discusses the chemical structure and properties of the natural insect toxins contained in *Chrysanthemum cinerariefolium* and gives examples of the development of synthetic pyrethroids. A translation of one paragraph reads as follows:

"The toxicities of pyrethroids for mammals are extremely low for skin contact and for intake by mouth. If on the other hand, pyrethrin II is injected intravenously into rats, the lethal dose is around 1mg/kg. [Administered by this method,] the substance is extremely toxic."

(v) *Veterinary Applied Pharmacology & Therapeutics (Fourth Edition), (Brander, Pugh and Bywater)*

This document is another one referred to by Mr Hacon and comprises just pages 468 and 469 of the above volume. On page 468 there is a passage, headed "Pyrethroids", which begins:

"Natural pyrethrums have been used as insecticides for more than a century."

It continues in the next paragraph:

"Since 1973, when Elliot reported in *Nature* on a photostable pyrethroid, a number of synthetic pyrethroids have been developed."

(vi) *The Third International Congress of Pesticide Chemistry - Helsinki, July 1974 - Abstract 338 "Acute Mammalian Toxicity of Natural and Synthetic Pyrethroids (Barnes and Verschoyle)*"

This document was referred to by both Mr Young and Mr Hacon but apart from its title, it includes nothing to help me determine what is meant by the term "pyrethroid"

(vii) *Pestic. Sci. 1989, **27**, 429-465, "Aquatic Organisms and Pyrethroids" (Hill)*

This document (which is also prior art document D4 cited by the applicants in their detailed grounds for revocation) reports studies into the effects of synthetic pyrethroid insecticides on aquatic ecosystems. Mr Hacon referred specifically to the following passage in the introduction:

"As the knowledge progressed over this period, so did the development of synthetic analogues of the natural pyrethroids. The early chemicals were like the natural product, photo-labile and thus mostly only suitable for 'indoor' uses."

(viii) *Pestic. Sci. 1989, **27**, 337-351, "The Pyrethroid: Early Discovery, Recent Advances and the Future" (Elliott)*

This paper (which is also prior art document D5) surveys the historical development of synthetic pyrethroids from the starting point of natural pyrethrins. Mr Hacon drew attention to a passage under the heading "Photolabile and photostable pyrethroids compared" on page 344 which begins:

"Pyrethroids such as pyrethrin I, allethrin and resmethrin are powerful insecticides with low toxicity to mammals, because mammals metabolize pyrethroids at one or several sites efficiently (Fig. 6)."

69 In all of these documents, the word "pyrethroid" is used to represent both the synthetic compounds and the natural substances, such as pyrethrins. Where it is desired to make a distinction between the two types of compound, the word is qualified as "synthetic pyrethroid" or "natural pyrethroid".

70 Having reviewed the evidence on this point, I am left to decide how to construe the word "pyrethroid", as it is used in the patent specification, on the balance of probabilities. I am not greatly helped in this by the evidence of the witnesses since they are split on what they understand by this word, but if anything I feel the preponderant view is that those skilled in the relevant art at the relevant time would have understood “pyrethroid” to cover synthetic and natural pyrethroids. That leaves the documents. From these I would conclude that at the priority date of the invention, "pyrethroid" was not uncommonly used by those skilled in the art to refer to both the natural and synthetic compounds.

71 Mr Young emphasised repeatedly the supreme importance of context in deciding the meaning to be attributed to a term. I quite agree with him, and accept that the context within which I must interpret the term “pyrethroid” is that of the patent. In that context, as he said, there are only examples of synthetic pyrethroids given; there is no mention of natural pyrethroids or pyrethrum in the patent. But equally, as Mr Hacon pointed out, there

is no explanation or definition of the term. In these circumstances, where a term is not defined in the specification, I must consider the extrinsic evidence, and having done so it seems to me that the skilled man would read the term "pyrethroid", absent any qualification, as embracing pyrethroids in general, natural and synthetic. Thus, I am driven to the view that this is the interpretation to be placed on the term in the patent. The absence of any explicit reference to or example of natural forms in the patent does not make this an easy decision, and I do not make it without some hesitation and after much careful reflection. Nonetheless, the opposite conclusion, that the patent only covers synthetic pyrethroids, would in my judgment be even more uncomfortable. On the balance of probabilities, I am persuaded that the unqualified use of the term "pyrethroid" in the patent would, at the priority date of the invention, have been understood by the skilled man to cover natural and synthetic pyrethroids. I might add that having reached this conclusion on the meaning of the term, I do not believe I need to consider the matter further in the framework of the *Improver* questions.

Novelty

72 By the time of the hearing, the applicants were attacking the novelty of claims 1 and 4 only and relying principally on five documents in support, namely D1, D2, D9, D7, D8. At an early stage in the hearing, Mr Young put down a marker that the Boxaspen paper (D9) had not been pleaded by the applicants as a document which would be used as part of an attack on novelty. Mr Hacon's response was that nobody had been taken by surprise by the document. Mr Young did not pursue the matter and addressed the Boxaspen paper in the context of novelty along with the other documents that had been formally pleaded by the applicants. In these circumstances, while I note Mr Young's marker, I do not take him to have been maintaining it, and so feel free to consider the applicants' novelty arguments based on this document.

73 For reasons of thoroughness and safety, I believe it will be helpful if I consider the question of novelty from two alternative starting points: first, on the basis that I am correct in construing "pyrethroid" in the patent as having a broad meaning embracing synthetic and natural pyrethroids; and secondly on the basis that I may be incorrect, and that the term "pyrethroid" has a narrow meaning embracing only synthetic pyrethroids.

Taking a broad meaning of "pyrethroid"

74 I have already summarised the documents relied on by the applicants. I shall consider first the Jakobsen and Holm paper (D2) and the Boxaspen paper (D9). Mr Young's view was that they did not include an enabling disclosure of the claimed invention, on the basis that they did not show a treatment for lice infestations, were not effective treatments as they gave at best 89% success rates, and were not used in a sea environment. Mr Hacon addressed each of those objections, largely on the basis that to be anticipatory, following *Evans Medical*, the disclosure needs to enable, not be enabled. Having considered both sets of submissions, it seems to me that each of documents D2 and D9 does disclose the use of natural pyrethroid to treat sea lice infestation in salmon in a seawater environment. Thus, claims 1 and 4 are not novel in my view if "pyrethroid" is given a broad meaning.

75 I should add that I do not consider that the novelty of claim 1 or claim 4 is impugned by the Horsberg thesis (D1). On this point, Mr Hacon said page 27 of the thesis discloses the

concept of using pyrethrum to treat seawater fish suffering from sea lice. With respect, I think the document suggests this concept but does not contain an enabling disclosure giving clear and unmistakable directions how to do it. Neither do I think that Fish Farming International (D7) or the Written Answer (D8) anticipate, and for the same reasons: neither one of these documents includes an enabling disclosure giving clear and unmistakable directions on how to use natural or synthetic pyrethroids in the treatment of sea lice infestations in seawater fish, such as salmon.

Taking a narrow meaning of "pyrethroid"

76 As I have said, in case I am wrong in the way I have construed the word "pyrethroid", I shall also consider Mr Hacon's fall-back submission to me on the question of novelty. Mr Hacon took the view that even if "pyrethroid" is given a narrow interpretation in the patent, that is it is limited to synthetic pyrethroids, claims 1 and 4 would be still be anticipated by the cited documents.

77 This fall-back position was explained by Mr Hacon largely by reference to the Horsberg thesis (D1,) but he made it quite clear that his argument applied equally to the other cited documents. The basis for this argument in the context of the Horsberg thesis rested on the statement in the thesis that "it seems probable that in the future synthetic pyrethroids will be of more interest than pyrethrum as possible delousing agents". From this Mr Hacon concluded that the Horsberg thesis contains a speculative disclosure of the concept of using a synthetic pyrethroid as a delousing agent for salmon. I would agree with Mr Hacon up to this point. Developing his argument further, Mr Hacon put forward the proposition that although a piece of prior art must be enabling to deprive an invention of novelty, *Evans Medical Ltd's Patent* had established that it does not have to have been enabled. Thus, if it is speculative that can be perfectly good enough.

78 Viewed in the context of the facts of this case, it seems to me Mr Hacon's point does not hold good. I believe that the circumstances here are somewhat different from those addressed by Laddie J in *Evans Medical*. The situation considered by Laddie J was one where there were accusations that the enabling disclosure in a priority document included fake results, but Laddie J nevertheless would have been ready to accept as enabling a description which fortuitously described something which works and how to do it. Mr Young's submission was that the Horsberg thesis does not meet that requirement, and I agree. In the Horsberg thesis there is no specific enabling disclosure, fortuitous or otherwise, concerning the use of synthetic pyrethroids; the passage Mr Hacon relies on is in my view simply not enabling, nor does it give clear and unmistakable directions. Mr Hacon suggested that any gap in enablement could be made up because skilled experts, such as Professor Stenersen, Dr Rodger and Mr Farrelly, would have no problem in carrying out tests to find the therapeutic window or optimum dosage range for a synthetic pyrethroid. That may be an appropriate consideration in relation to inventive step, but not in relation to novelty. Thus, I do not accept Mr Hacon's fall-back submission that the Horsberg thesis would destroy the novelty of claims 1 and 4 when restricted to the use of synthetic pyrethroids.

79 The other citations on which Mr Hacon hoped to rely for a novelty attack on claims 1 and 4 included D2 and D9. Mr Young said that these as well as D1 related to the pyrethrum exercise, which I took to mean they did not involve synthetic pyrethroids. Mr Hacon

admitted they contain no express teaching of using synthetic pyrethroids but invited me to apply his fall-back position to these documents as well as to D1. I have done so, and reached the same conclusion, and for the same reasons. Neither document D2 or D9, it seems to me, would enable the working of a method within claims 1 and 4.

80 Finally under novelty, I need to consider again documents D7 and D8. Both contain a reference to a research programme involving the evaluation of a pyrethroid, and mention that the studies are at a preliminary stage. Mr Hacon cited for example Dr Goksøyr as saying that these articles would have given him the concept of using synthetic pyrethroids to treat lice in salmon. Mr Young called D7 and D8 journalistic references or reports which did not disclose the full inventive concept of claims 1 and 4. I would not be so dismissive of their nature - journalistic reports can constitute anticipatory disclosure - but I do agree they do not in this case disclose the invention claimed.

81 Accordingly, I do not believe that any of the cited documents would destroy the novelty of claims 1 and 4 if the term "pyrethroid" appearing in them is, contrary to my finding, construed narrowly.

Inventive step

82 I turn now to the question whether the claimed invention involves an inventive step. In the event that I took a narrow view of the meaning of the word "pyrethroid", Mr Hacon's submission was that the invention of claim 1 and all the other claims was nevertheless obvious. I have of course already concluded that the word "pyrethroid" should be interpreted broadly to embrace both synthetic and natural pyrethroids. However, it seems to me preferable first to consider whether, on a narrow interpretation of the word, the invention as claimed in claims 1 to 14 involves an inventive step. If the claims are obvious on that basis, they will remain so on a wider interpretation of "pyrethroid".

83 Mr Hacon's case on inventive step relied on three starting points, which when individually combined with common general knowledge, in his submission, rendered the invention obvious. These starting points were:

(i) the Horsberg thesis (D1);

(ii) the Jakobsen and Holm paper (D2) or the Boxaspen paper (D9); or

(iii) Fish Farming International (D7) or the Written Answer (D8).

84 Early in the hearing Mr Young put down a marker that the Horsberg thesis, Fish Farming International and the Written Answer had not been pleaded by the applicants as a starting point for obviousness. However, Mr Young did not press this procedural point against these documents and took the opportunity to respond to the submissions made by Mr Hacon based on them. Therefore, I will consider the inventive step of the invention claimed in the patent against the disclosure in the various documents as relied on by Mr Hacon.

The inventive concept

85 To apply the four *Windsurfer* steps I must first identify the inventive concept of the claimed invention. As I have already noted, the patent contains four independent claims, and it is of course to the claims that I will need to turn to determine obviousness. However, I am drawn to the statement in the patent that:

> "... we have found that pyrethroids, particularly cypermethrin and alphacypermethrin, can be administered to salmon and other seawater fish in a manner which is highly effective in the control of sea lice in the salmon and other fish while being much less toxic to the fish themselves than dichlorvos."

At the hearing Mr Hacon identified the inventive concept concisely as the use of a synthetic pyrethroid to treat seawater fish for sea lice, and more particularly overcoming an alleged prejudice against doing so. I note that Mr Young did not disagree with this, although he did have a good deal to say about what was needed by way of enablement, for example what levels of effectiveness were required. I shall return to this and other considerations later. For the moment I shall work on the basis that in its broadest aspect the inventive concept lies in the use of a synthetic pyrethroid as a delousing agent for seawater fish.

The common general knowledge

86 In order to apply the *Windsurfer* reasoning I also need to have a clear understanding of what was common general knowledge at the priority date of the inventive concept, that is in March 1991. In his submission to me on this matter Mr Young referred me to the established principles for determining common general knowledge as endorsed by the Court of Appeal in *Beloit v Valmet*. In particular, Mr Young took me to a passage in *Beloit v Valmet* where Aldous LJ refers to *General Tire* and to the statements made by Luxmoore J in *British Acoustic Films*, which I have already referred to above.

87 Based on these principles, Mr Young stated that the relevant common general knowledge on the facts of this case was that sea lice infestation was a serious problem to salmon fish farming and that an effective treatment had to target more than one stage in the life cycle of sea lice. As of March 1991 the state of the art treatment for sea lice was the organophosphate dichlorvos, administered as a bath treatment, but sea lice were developing resistance to this treatment, which was also known to be hazardous to man and to have environmental problems. Oral treatments were preferable to bath treatments as being more reliable and more easily applied. It was also part of the common general knowledge that pyrethrum was being investigated as a new treatment against sea lice. It was also known that pyrethroids were a class of pesticides which were highly toxic to fish and other aquatic organisms. Mr Hacon did not challenge this view but sought to clarify the point made by Mr Young about the toxicity of pyrethroids. On numerous occasions during the course of the hearing, Mr Hacon observed that anything is toxic in high concentrations and less or non-toxic if you reduce the concentration. Moreover, when treating salmon for sea lice using pesticides, such as dichlorvos, the skilled person would recognise the importance of the relative toxicity of the pesticide to salmon and sea lice. I accept that Mr Young's description with Mr Hacon's added clarification is a fair assessment of what was common general knowledge in March 1991.

88 However, I consider that I can and should add something more about the common general knowledge as it stood at the relevant time concerning natural and synthetic pyrethroids, based on the extensive evidence provided in this case. Natural pyrethroids, by which I mean pyrethrum and its constituent pyrethrins, were considered too expensive and too unstable in light to be used for controlling agricultural pests. Moreover, they were commonly used with piperonyl butoxide which allowed the use of lower concentrations of the natural pyrethroid than would otherwise have been necessary. Synthetic pyrethroids with characteristically high activity against insects and low mammalian toxicity were first developed around 1973. Some of those developed before 1991 are more toxic than the pyrethrins and some do not require the use of a synergist.

Differences between the cited matter and the alleged invention

89 The next step in applying the *Windsurfer* test is to identify the differences between the cited matter and the alleged invention. I have already summarised the content of the Jakobsen and Holm paper (D2) and the Boxaspen paper (D9) but to recap both these papers describe trials using pyrethrum to delouse salmon, which to a degree were effective. The Horsberg thesis (D1) mentions studies on the potential of pyrethroid pesticides, particularly pyrethrum, as delousing agents in salmon. One of the relevant articles in Fish Farming International(D7) reports work on the use of pyrethrin but the other article reports on studies evaluating a pyrethroid. The Written Answer (D8) also mentions the evaluation of a pyrethroid.

90 Mr Hacon concluded that the alleged difference between the citations and the inventive concept lay in recognising that a therapeutic window exists enabling synthetic pyrethroids to be used to treat sea lice infestation in sea fish. In this context, "therapeutic window" means the difference between the minimum concentration or exposure to be toxic to sea lice and the maximum before it becomes toxic to the fish. Although this is a highly relevant consideration, I would approach the point slightly differently. There is no clear and unambiguous disclosure in any of the cited documents of using a synthetic pyrethroid to treat salmon infested with sea lice. From this I would conclude that the principal difference between the cited matter and the inventive concept as identified above resides in the use of synthetic rather than natural pyrethroid.

Obvious to try

91 The final step in the *Windsurfer* process requires me to consider whether the difference I have identified would have constituted a step which would have been obvious to the skilled person. The question I must answer is whether it would have been obvious to the skilled person to use a synthetic pyrethroid to treat seawater fish, such as salmon, for sea lice infestation. More particularly, having regard to the common general knowledge and disclosure in the documents relied on by the applicants, which relate to the use of a natural pyrethroid, pyrethrum, would it have been obvious to the skilled person to try a synthetic analogue for the same purpose with a reasonable expectation of success?

92 The applicants' position on this question was a very simple one. Mr Hacon put it that each of D1, D2, D9 states that pyrethrum has a therapeutic window making it suitable for treating sea lice; synthetic pyrethroids were developed to have the same effect but be more photostable; so synthetic pyrethroids are synthetic photostable substitutes for pyrethrum.

In his words, the concept of using natural pyrethroid to treat fish infested with sea lice was known at the priority date of the patent and so it was obvious to use a synthetic analogue for the same purpose. However, Mr Young did not see it in such simple terms and his submission to me was that until the present invention had established the surprisingly wide safety margin of pyrethroids in terms of their high LD_{50} value for seawater fish and their low LD_{50} value for sea lice, the skilled person would not have thought that pyrethroids would provide an effective treatment for sea lice infestation. Without this knowledge the skilled person would have been deterred from using pyrethroids because of their known high toxicity to fish.

93 I find Mr Young's position somewhat difficult to accept. If someone had done trials and found that pyrethroids provided a wide safety margin, I cannot see what would be left for the skilled person to try before reaching the present invention. Moreover, as Mr Hacon pointed out more than once, anything is toxic at high enough concentrations or dosages but would not be toxic at a low enough concentration or dosage. Therefore I am drawn to the applicants' position and will consider whether it would have been obvious, in the face of the disclosure in the documents relied on by the applicants and the common general knowledge at the relevant time, to use a synthetic analogue of pyrethrum for the treatment of sea lice in seawater fish

94 I will begin by considering the Jakobsen and Holm paper (D2) and the Boxaspen paper (D9), which separately comprise one of the applicants' starting points. I have already summarised the content of these papers, which may be said to relate to the Austevoll research, but to recap they both demonstrate that pyrethrum can be used as an agent to kill sea lice on salmon.

95 In essence it is the applicants' case that because the Austevoll research showed that pyrethrum could be used with some success to delouse salmon, there would have been a reasonable expectation that treatments using synthetic pyrethroids would have the same effect. However, Mr Young dismissed each of the two papers D2 and D9 as basic write-ups rather than scientific papers and pointed to an opinion expressed by Dr Rodger that the reported outcome of the Austevoll research was unattractive in practical terms. To reinforce Dr Rodger's opinion, Mr Young went on to draw my attention to an acknowledgement in the D2 and D9 papers that introductory tests had shown that emulsified pyrethrum was toxic to fish. Despite the applicants' witnesses under cross-examination attributing this to too high a concentration, according to Mr Young a skilled person faced with this information would take it as implying that the only way to use pyrethrum as a pesticide, so as not to kill salmon, was via a surface layer of oil. Even then, Mr Young pointed out, there was a warning that the treatment should be used with utmost caution until the trials with pyrethrum had been completed and the treatment had been finally approved. Mr Young also highlighted a comment in Professor Stenersen's first statutory declaration that the method of administration using an oily layer as described in the two papers was not the best route of administration and that a better result could be obtained by quickly turning the fish around in a bath of pyrethrum. When cross-examined Dr Horsberg seemed to support the proprietor's viewpoint when he said that he would not have recommended the treatments reported in the two papers to every Norwegian fishery because the results were not good enough for them to be regarded as successful treatments. Nevertheless, Dr Horsberg made it clear that in his opinion the Austevoll research had demonstrated that pyrethrum was effective to kill sea lice. From all of these opinions and

views Mr Young concluded that none of the evidence held the sufficient expectation of a practical approach to treating infestations of sea lice using synthetic pyrethroids.

96 Another point which Mr Young considered important was that pyrethrum was mixed with piperonyl butoxide in the trials reported in the Jakobsen and Holm paper and in the Boxaspen paper. While piperonyl butoxide is a well known synergist and antioxidant for pyrethrum, in his oral evidence Dr Rodger stated that piperonyl butoxide also had insecticidal activity in its own right and was a licensed product in 1991 for various types of mange in cats and dogs. Dr Rodger admitted though that he had no personal experience of using this licensed product. In support of Dr Rodger's statement that piperonyl butoxide was itself an insecticide, Mr Young produced an extract from Chapter 14 ("Potential of Piperonyl Butoxide for the Management of the Cotton Whitefly, *Bemisia tabaci*" - Devine and Denholm) of a book having the title "Piperonyl Butoxide The Insecticide Synergist" and edited by Denys Glynne Jones. The ability of piperonyl butoxide to act as an insecticide as well as a synergist was something that Mr Young explored with the applicants' witnesses. Under cross-examination, Professor Goksøyr answered in the clearest of terms that piperonyl butoxide was not a pesticide, and both Professor Stenersen and Dr Horsberg stated that they had never heard of piperonyl butoxide being used as pesticide in its own right. These latter two witnesses also provided a clear explanation of how piperonyl butoxide acts synergistically with pyrethrum by hindering the process by which insects can metabolise and so detoxify pyrethrum.

97 Despite receiving no support from the majority of the witnesses on the insecticidal activity of piperonyl butoxide *per se*, Mr Young opined that the skilled person would draw no clear conclusions about the effectiveness of pyrethrum from the reports of the Austevoll research, firstly because piperonyl butoxide is a pesticide in its own right and secondly because this synergist allowed the use of lower dosages of pyrethrum than would have been possible without it. Therefore in Mr Young's view, if you took all these factors into consideration, there was no basis for a skilled person to believe that there was a reasonable chance that a synthetic analogue of pyrethrum would be an effective treatment for sea lice. Mr Hacon made the reasonable point that the inventive concept did not demand use of pyrethroid alone, so reliance on the presence also of piperonyl butoxide would not matter.

98 I turn now to another of the applicants' starting points, the Horsberg thesis (D1). Mr Young described this as a contemporaneous reaction to the Jakobsen and Holm paper (D2). In particular, he likened the Horsberg thesis to a mirror for testing what one would have considered obvious to try with a reasonable expectation of success based on the teachings of this paper. In developing his submission, Mr Young quoted the following passage from the thesis:

> "Preliminary clinical trials with pyrethrum administered on the water surface using oil as the vehicle, have demonstrated a certain clinical effect on sea lice (Jakobsen & Holm, 1990).
>
> Pyrethrum is, however, a mixture of insecticidal agents which are extremely toxic to fish. ... Being highly toxic does not necessarily exclude a substance from therapeutic use, since it is the margin between toxic dose for the parasite and the toxic dose for the fish that is important. This margin remains, however, to be determined for pyrethrum. The extremely high toxicity towards several non-target aquatic

organisms also raises the question of possible adverse impact of any solution released into the environment.

In spite of the rather low toxicity in mammals, ... pyrethrum may cause harmful effects in man. Allergic reactions, such as contact dermatitis, often aggravated by exposure to sunlight, have been frequently reported ....."

99 Mr Young saw this passage as indicating that the authors of the thesis were extremely sceptical about the pyrethrum work and the possibility of using pyrethroids as a pesticide for sea lice treatment. Mr Hacon's position was somewhat different. He pointed to Professor Stenersen's view that having been told by D1 that a therapeutic window existed, it would be relatively easy to design trials to ascertain it. He also drew attention to Dr Rodger's comments that such work would be time-consuming but would be a matter of routine testing and the expectation of success would be high.

100 Mr Young then took me to the overall conclusion in the Horsberg thesis, which indicates that future needs are for two different compounds. One type should have a quick knock down effect for treating rapidly growing parasitic problems and the other should be an agent, preferably to be given orally, designed for the control of more slowly growing parasitic problems. Mr Young pointed out that there was no indication that the authors thought that pyrethrum or synthetic pyrethroids might fit this bill and provide an alternative treatment to dichlorvos for sea lice problems. Thus, overall Mr Young concluded that the thesis provides a good illustration that its authors were not interested in the use of pyrethroids and held no great expectation that they would provide a successful treatment.

101 This leaves the third basic starting point relied on by the applicants, namely Fish Farming International (D7) or the Written Answer (D8). As I have mentioned, Fish Farming International reports on research in Norway on the use of pyrethrin to control sea lice infestation in farmed salmon and preliminary studies in Scotland to evaluate a pyrethroid for the treatment of sea lice. The Written Answer also refers to studies in Scotland with a pyrethroid. Neither of these documents contains more that a simple indication that research into the use of pyrethrin or a pyrethroid was in hand. Thus in my view, if I do not find a lack of inventive step on the basis of the other documents relied on by the applicants, this more distant basic starting point will not get them any further. I therefore do not propose to consider this third basic starting point further.

102 In reaching a conclusion on whether it would have been obvious to a skilled person to try a synthetic pyrethroid to treat sea lice infestations in seawater fish, I must first answer the question, posed by Mr Young, why if it was obvious to try, the Austevoll research group, who had conducted trials with pyrethrum, did not themselves investigate whether a synthetic pyrethroid could be used. I find the answer to this question in the written evidence of Professor Goksøyr who explains that the Austevoll researchers were not interested in synthetic pyrethroids because their work was sponsored by Norsk Pyrethrum AS, which was an importer of pyrethrum into Norway. In cross-examination Professor Goksøyr provided further information and referred to the researchers buying a bottle of pyrethroid which they wanted to use but did not do so because the sponsorship kept the focus on pyrethrum. Thus, the fact that the Austevoll group did not extend their research to the use of synthetic pyrethroids cannot be taken as indicating that it was not obvious to

them to try. Indeed, Professor Goksøyr's statement about the bottle of pyrethroid seems to suggest the opposite.

103 I need now to consider whether the presence of piperonyl butoxide in a mixture with pyrethrum, as used in the Austevoll research, would have deflected the skilled person from having a reasonable expectation that a synthetic analogue of pyrethrum would provide a successful treatment. Although not formally submitted as evidence I have considered the extract from the book "Piperonyl Butoxide The Insecticide Synergist", which Mr Young referred the witnesses to and which he handed up to me. I have noted that it contains a statement in relation to the Cotton Whitefly that "... PBO can inflict mortality in its own right ...". However, it seems on reading further that piperonyl butoxide is not effective against all pests. I also have Dr Rodger's evidence that piperonyl butoxide was licensed for the treatment of various types of pet mites or mange though he had himself not used it for that, but from this I still cannot conclude that piperonyl butoxide has any pesticidal activity against sea lice. Then there is the oral evidence of Professor Goksøyr, Professor Stenersen and Doctor Horsberg, all of whom are experts in the technical field but who were aware of piperonyl butoxide as a synergist but were not aware that it might be a pesticide in its own right. It therefore seems to me that we have a situation where the skilled person would not have attributed any insecticidal activity to piperonyl butoxide in the reports of the Austevoll research, even if in fact it had this activity in relation to sea lice. As a consequence, in my view the skilled person would have attributed the insecticidal activity wholly to the pyrethrum in a way which would have been fully consistent with the manner the research is reported.

104 Then there is the question whether the skilled person would have been deterred from trying a synthetic pyrethroid because he recognised that by using the piperonyl butoxide synergist, the researchers had been able to use lower concentrations of pyrethrum than would have otherwise been possible. In 1991 the skilled person would have known not only that the toxicities of pyrethrum and the synthetic pyrethroids were not all the same but also, as stated in the Horsberg thesis, that:

> "Being highly toxic does not necessarily exclude a substance from therapeutic use, since it is the margin between the toxic dose for the parasite and the toxic does for the fish that is important."

Thus, at the outset the skilled person would have realised the need to take account of the different toxicities of pyrethrum and the synthetic pyrethroids, and need for experiments to determine if there was a dosage for a synthetic pyrethroid that was toxic to sea lice but not to the fish. For this reason I consider that the skilled person would have thought to try synthetic pyrethroids and would not have been deterred from trying due to the prior use of piperonyl butoxide with pyrethrum.

105 I turn now to Mr Young's submission that the trials reported in the Jakobsen and Holm paper (D2) or the Boxaspen paper (D9) did not hold out the prospect of a practical treatment using a synthetic pyrethroid. As Mr Young pointed out, the best effect obtained was 89% sea lice mortality, and Dr Rodger had said this was not good enough for the treatment of lice infestation from a practical point of view. Mr Hacon’s response was that a commercial level of delousing was not required for a disclosure to enable the claimed

invention. As he put it, the inventive step is the concept of using a pyrethroid to treat fish for sea lice; it is not a means of achieving more than 89% reduction in lice.

106 For my part, I accept that the general view of the witnesses was that the work described in these papers did not represent a commercially viable treatment for sea lice infestations. Nevertheless, I do not accept that a shortfall in the efficacy of the treatment, or a less than ideal method of administration, would deter a skilled person from trying a synthetic pyrethroid provided the effectiveness which had been obtained was sufficiently encouraging. In my view the results described in these papers, showing that pyrethrum was effective to kill sea lice without having an unduly adverse effect on the salmon, would provide sufficient encouragement for the skilled person to try using synthetic pyrethroids. According to Professor Goksøyr this is exactly what the Austevoll team wanted to do when they obtained their bottle of pyrethroid. Moreover, since the problems associated with natural pyrethroids, due for example to their lack of stability, were common general knowledge, I consider that the skilled person would recognise that synthetic pyrethroids might offer a better prospect for a commercial product. I find some support for this in the following passage taken from the Horsberg thesis:

> "Due to the instability of the natural pyrethrins and the need for the addition of several chemicals to overcome this, synthetic derivatives are used as insecticidal agents. These include compounds such as deltamethrin, permethrin, cypermethrin and fenvalerate, and more recent products such as flucythrinate, fluvalinate etc. The synthetic pyrethroids are more stable than the pyrethrins, and are equally or more potent pesticides. It seems probable that in the future, synthetic pyrethroids will be of more interest than pyrethrum as possible delousing agents."

107 I must now address Mr Young's point that the Horsberg thesis (D1) indicates extreme scepticism about the pyrethrum work and prospects for pyrethroids as a successful treatment for sea lice. I do not agree with Mr Young on this point and to explain why it is helpful to quote from the overall conclusion in the thesis:

> "Because of its high acute toxicity in mammals, fish and invertebrates, as well as the possible development of resistance, dichlorvos cannot be considered as the ultimate solution of the sea lice problem. It should be replaced by less dangerous compounds as soon as possible. We have presented some candidates and have carried out kinetic studies and preliminary clinical trials on some of them (Papers 7, 8 and 9). We have, however, not reached a definite conclusion as to which compound(s) should replace dichlorvos. There is a need for two different kinds of compound. One type should have a quick knock down effect, for the treatment of rapidly growing parasitic problems. This might be dichlorvos, although one would prefer a less toxic compound, e.g. a compound within the carbamate class of insecticides. The other should be an agent, preferably to be given orally, designed for the control of more slowly growing parasitic problems. This might be an insect growth regulator of the chitin inhibitor type."

108 It is clear from this that the hunt was on for something to replace dichlorvos but the authors of the thesis did not reach any conclusion about what this replacement should be. While there is nothing in the passage I have quoted above to indicate that the authors expected

pyrethroids to be the successful replacement for dichlorvos, nevertheless by addressing pyrethroids in their thesis, they had pyrethroids in mind as serious possible candidates.

109 Before I draw any final conclusions on the obvious-to-try question I must also consider the submission made to me on the commercial success of the cypermethrin-based product of the invention, "Excis". Ms Hardwick provided evidence that Excis was a commercial success to the extent that it displaced earlier products from the market to a significant extent. For the applicants' Mr Hacon accepted this but in his opinion this did not prove that there was anything inventive about Excis. For the proprietor Mr Young also accepted that the relatively short time that had elapsed between the priority date of the invention and the publication of the Horsberg thesis, the Jakobsen and Holm paper, and the Boxaspen paper, did not allow a long-felt want argument to be advanced of the sort that if the present invention was so obvious, why had nobody tried it before. I agree with both these points and so conclude that consideration of the commercial success of Excis does not help me determine whether or not the present invention is obvious.

110 I will now summarise some of my main conclusions, obtained by following the *Windsurfer* process, on those matters which have a bearing on whether it would have been obvious, in the face of the disclosures in the documents D2, D9, D1 separately relied on by the applicants and the common general knowledge at the relevant time, to use a synthetic analogue of pyrethrum for the treatment of sea lice on seawater fish:

(a) The Austevoll research reported in D2 and D9 was focused on and restricted to the use of pyrethrum because its sponsorship did not permit an extension of the work to synthetic pyrethroids;

(b) The use by the Austevoll research group of piperonyl butoxide mixed with the pyrethrum would not have created any doubts in the mind of the skilled person that the active pesticide in the mixture was the pyrethrum. Moreover, there was a reasonable expectation that synthetic analogues of the natural material could be used at appropriate dosage levels which could routinely be established;

(c) The Austevoll research did not provide a commercial level of treatment for sea lice, both from the point of view of the method of treatment and its efficacy. Nevertheless, this research established that pyrethrum could be used to kill sea lice on salmon without an unduly adverse effect on the fish;

(d) The Horsberg thesis (D1) identifies synthetic pyrethroids as one of several possible candidates for the future treatment of sea lice infestations in salmon, and says that it seems probable that in the future synthetic pyrethroids will be of more interest than pyrethrum as possible delousing agents.

111 On the basis of these considerations, I come to the conclusion that against the background of the common general knowledge as it existed in 1991 and when faced with the disclosure in either the Horsberg thesis, or the Jakobsen and Holm paper, or the Boxaspen paper, the skilled person would have thought of using a synthetic pyrethroid instead of pyrethrum with a reasonable expectation of success. It therefore follows that I consider the broad inventive concept of the patent, that is the use of a synthetic pyrethroid as a delousing agent for seawater fish, to be obvious.

112 I must now consider what this means for the specific claims in the patent, which I shall take in turn:

Claim 1

This claim simply embodies the broad inventive concept which I have already found to be obvious and so it follows that the claim itself lacks an inventive step.

Claim 2

This claim specifies that the pyrethroid pesticide is cypermethrin or alphacypermethrin. Mr Hacon cited document D6 in support of the obviousness of this claim. It refers to the use of cypermethrin and its effect on fish, although as Mr Young pointed out this is in a fresh water environment. In his opening submission Mr Hacon described both of these compounds as well known and commonly used pesticides. This is consistent with the background art described in the patent. Having considered these arguments, on the basis of common general knowledge I consider that claim 2 does not provide an inventive step.

Claim 3

This claim specifies that the composition containing the pyrethroid pesticide is a composition to be administered orally. Again in his opening submission Mr Hacon stated that oral administration is one of the standard ways of administering a delousing agent, referring to Dr Rodger's evidence. This was not challenged by Mr Young, who indeed had referred to the benefits of oral treatment in his review of the common general knowledge. On the basis that the claim only relates to something which is standard, I consider it obvious.

Claim 4

This claim specifies that the seawater fish is salmon. The documents which the applicants have advanced to show that the invention lacks an inventive step specifically concern the treatment of salmon or more generally salmonid. Therefore claim 4 lacks an inventive step.

Claim 5

This claim is restricted to the use of cypermethrin or alphacypermethrin administered orally within a specified range of dosages. I have already decided that the selection of cypermethrin or alphacypermethrin and that formulation as an orally administered composition do not provide an inventive step. This leaves just the dosage rate to be considered, and in his submission Mr Hacon stated that finding the right dosage rate would be a matter of common knowledge. He cited in support Dr Rodger and Professor Stenersen under cross-examination. He pointed to Professor Stenersen's view that having been told by D1 that a therapeutic window existed, it would be relatively easy to design trials to ascertain it. He also drew attention to Dr Rodger's comments that such work would be time-consuming but would be a matter of routine testing and the expectation of success would be high. He also cited paragraph 33 of Mr Farrelly's expert report where he makes clear that the optimum dosage range for each compound would be a routine matter. After

considering the papers D2 and D9 in the light of the expert evidence, I am satisfied that it would be a matter of routine experimentation to identify the optimal dosages for cypermethrin or alphacypermethrin. Therefore I find that claim 5 lacks an inventive step.

Claim 6

This claim involves suspending a pyrethroid in water for the treatment of salmon. Mr Hacon submitted that this is one of the standard ways of using pesticides. Much was said during the hearing about the rediscovery in 1987 at the Austevoll Aquaculture Research Station that pyrethrum emulsified in water is poisonous to fish. However, as Dr Rodger confirmed when cross-examined by Mr Hacon, a suspension and an emulsion are not the same thing: put simply, a suspension is solids in a liquid and an emulsion is a liquid in a liquid. Therefore, I cannot see that this rediscovery by the Austevoll researchers concerning the toxic effect of an emulsion has a bearing on the use of a pyrethroid in suspension.

Mr Hacon cross-examined Dr Rodger on this matter of suspensions. In the context of using a bath treatment for dealing with an acute infection, Mr Hacon asked Dr Rodger "Then you would be putting the fish into a suspension of the agent?", to which he received the answer "that's right". That suspending pesticides in water was a standard way of using them was not challenged, and I conclude that claim 6 is obvious because it is characterised by something that is no more than a standard method of administration.

Claim 7

This claim specifies cypermethrin and alphacypermethrin and, as with claim 2, I find that this feature does not provide an inventive step.

Claim 8

This claim specifies a range of concentrations at which the pesticide is administered. I also find this claim obvious for the reasons explained above in connection with claim 5.

Claim 9

Like claim 6, this claim involves the use of a pyrethroid pesticide suspended in water and I find it obvious for the reasons already given in the context of claim 6.

Claim 10

This claim specifies cypermethrin and alphacypermethrin and, as with claims 2 and 7, I find that it does not provide an inventive step.

Claim 11

This claim is characterised by external administration of a suspension to salmon. The Austevoll research with its layer of oil or bath treatment administered pyrethrum externally and I have already accepted that there is no invention in using the pyrethroid in suspension.

I conclude therefore that external administration of a pyrethroid in suspension does not provide an inventive step.

Claim 12

This is a claim for a food composition containing a pyrethroid pesticide. Neither side addressed me specifically on this particular aspect of the invention although Mr Hacon did suggest that like claims 7 to 11, 13 and 14 it merely repeated what was found in claims 1 to 6. Of these earlier claims, claim 3 to oral administration is the closest to claim 12 and I have already concluded that this earlier claim is obvious because this method of administration is conventional. The question then arises how would you get a salmon to take a pesticide orally, and it seems a standard method would be by combining it with its food. Therefore, once again on the basis that oral administration of pesticides is a standard procedure, I do not consider that claim 12 contains an inventive step.

Claim 13

This claim is another that merely specifies cypermethrin and alphacypermethrin and so, as I have already done with claims 2 and 7, I conclude that there is no inventive step in claim 13.

Claim 14

This is another claim that specifies a range of dosages and for the reason already given above in relation to claim 5 I consider that this claim lacks an inventive step.

113 For the avoidance of doubt I should repeat that although I have concluded that all the claims lack an inventive step on the basis of a narrow interpretation of the word "pyrethroid" in the patent, that is one embracing only synthetic pyrethroids, it follows in my view that the claims would also be obvious if the word "pyrethroid" was interpreted more broadly to include natural pyrethroids, as I have found it should.

Summary of conclusions

Novelty

114 The applicants' attack on novelty was in respect of claims 1 and 4 only. I concluded that the word "pyrethroid" as used in the claims was understood at the priority date of the application to embrace natural pyrethroids, such a pyrethrum, as well as the synthetic analogues. On that basis, I found that claims 1 and 4, which are of the Swiss-type, were not novel in the light of the disclosure of the Jakobsen and Holm paper (D2) or the Boxaspen paper (D9). In case I were incorrect in my interpretation of the word "pyrethroid", I also considered the novelty of claims 1 and 4 on the basis that they were limited to the use of synthetic pyrethroids. In that event, I found those two claims did not lack novelty over the documents relied on.

Inventive step

115 When considering whether the present invention involved an inventive step, I did so principally on the basis of the narrow interpretation of the word "pyrethroid". In other words I considered whether it would be obvious to use a synthetic pyrethroid to treat seawater fish for sea lice. By applying the four *Windsurfer* steps, I concluded that the skilled person would have thought that there was a reasonable expectation that a synthetic pyrethroid could be used as an alternative to natural pyrethroid for the treatment of sea lice infestation in seawater fish. Having reached this conclusion and taking account of what was conventional or common general knowledge, I found that claims 1 to 14 all lack an inventive step. This conclusion was, as I say, on the basis of a narrow interpretation of "pyrethroid". Given that I prefer a broader interpretation of the term, this approach to inventive step is arguably safe but artificial. The finding of lack of inventive step can only be stronger if the word "pyrethroid" is given the broad interpretation in the claims to include natural as well as synthetic compounds which I believe is justified.

116 Subject therefore to what I say below about the possibility of amendment, the patent is invalid and stands to be revoked under section 72.

Amendment

117 In the course of his submissions, Mr Young advanced a number of what he called "citadels", that is to say sequential fall-back positions made by combining various claims and intended for consideration were I to find the main claims invalid. Since I have found all the claims lacking at least in inventive step, it is not necessary or useful for me to consider the citadels he proposed.

118 I believe it is unlikely, in view of my findings, that an amendment can be found to save the patent. However, it would I think be wrong of me to dismiss the possibility entirely without having given the proprietor an opportunity to comment on the matter, either in terms of whether a saving amendment exists, or whether discretion should be exercised to permit it. Of course the applicants may also have something to say on these matters.

119 **In these circumstances, and bearing in mind the period for appeal, I allow the proprietor two months from the date of this decision within which it may file proposals for amendment of the patent which overcome the defects I have found, and submissions as to why discretion should be exercised to allow them. If they do so, the applicants shall have one month in which to file a response. If the proprietor fails to file proposals for amendment in the time I have allowed, the patent will be revoked.**

Costs

120 Both sides seek an award of costs in their statement of case, and at the hearing both Counsel accepted that any costs award should be based on the scale published by the comptroller from time to time. This scale reflects the long-standing practice in proceedings before the comptroller that costs awarded represent a contribution and are not intended to be compensatory. As the present proceedings were commenced before 22 May 2000, the appropriate scale is that at annex B to the Office's Tribunal Practice Notice 2/2000.

121 As I have found in favour of the applicants, it is clear that an award of costs should be made in their favour. I therefore order that the proprietor shall pay the applicants the sum

of £1300 as a contribution to their costs. The payment shall be made within seven days of the expiry of the appeal period unless an appeal is lodged, in which case payment may be suspended pending the appeal.

Appeal

122 This being a decision other than on a matter of procedure, the period within which any appeal shall be filed is six weeks from the date of this decision.

Dated this 18th day of March 2002

S N DENNEHEY
Divisional Director, acting for the comptroller

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