Ancare New Zealand Ltd v Cyanamid of NZ Ltd

Court of Appeal Wellington
26, 27, 28 June; 17 July 2000
Gault, Henry and Thomas JJ

Patents – Revocation – Obviousness – Test for obviousness – Determining the inventive step – Whether to be determined by reference solely to scientific knowledge – Importance of market developments – Patents Act 1953, ss 41(1)(e) and (f).

Patents – Amendment – Procedure for application to amend patent – Whether effect of order for revocation should be delayed while application for amendment pursued – Patents Act 1953, ss 39 and 40(1).

Ancare New Zealand Ltd (Ancare) held a patent for a liquid combination of various pharmaceutical (anthelmintic) compositions relating to the treatment of parasitic worms (helminthiasis) in farm animals. The patent was for a broad-based anthelmintic formulation in liquid form to control both tapeworm and roundworm. In particular, the claimed invention was to combine the anthelmintic praziquantel, which was effective in treating tapeworm, with at least one of a number of listed anthelmintic formulations, which were successful in treating roundworm. Novartis New Zealand Ltd (Novartis) and Cyanamid of NZ Ltd (Cyanamid) applied to the High Court under the Patents Act 1953 to revoke this patent on a number of grounds, including claims that the patent was invalid because of lack of novelty or prior publication (s 41(1)(e)) and obviousness (s 41(1)(f)). Ancare in turn applied to amend the patent under s 39 of the Patents Act 1953 in the event that the High Court should decide to revoke the patent. At the hearing of the application to revoke the patent, the High Court held that it was invalid on the grounds of lack of novelty or prior publication, and that it was obvious. In finding that the invention lacked novelty the High Court held that elements of Ancare's patent had been disclosed by the prior publication of a patent belonging to Bayer. With regard to obviousness, the High Court held that the combination of praziquantel with one of the other listed anthelmintics in a liquid form would have been an obvious approach for a skilled person or team to take if they intended to provide a combined drench for controlling both roundworm and tapeworm. An order was made for revocation of the patent. However, as argument had not been heard on Ancare's application to amend the patent, it was directed that the order was not to take effect if the application for amendment was pursued.

Following judgment Ancare made a new application for amendment of the patent. Ancare also appealed the original finding of the High Court. The Court of Appeal held that the issues concerning the validity of the patent should not be ruled upon until the proposed amendment had been dealt with by the

High Court. At a further hearing the High Court rejected the proposed amendments as they would not overcome the invalidity it had earlier found on the ground of obviousness. The appellant appealed both decisions of the High Court.

Held: 1 The test for obviousness was a question of fact: whether a person or team skilled in the field but not inventive, and invested with the common general knowledge available in that field at the priority date, would have seen the alleged inventive step as obvious and would have recognised it as something that could be done or was at least worth trying, without bringing any inventiveness to bear. The skilled person or team to be postulated in the case was one sufficiently interested to read the Bayer patent and to consider how the treatments might be combined to produce a broader spectrum of activity. The element of inventiveness necessary to resist such an attack was not high, but in deciding what was already known or used, the Court was not restricted to the scientific literature but had to consider what was happening in the market. There was no error in framing the question in this case as whether it would be obvious in seeking a product for treating both roundworm and tapeworm to formulate a composition of the two treatments (see paras [43], [44], [62], [66], [67]).

Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] RPC 59 (CA), *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195 (CA), *Mölnlycke AB v Procter & Gamble Ltd* [1994] RPC 49 (CA) and *Samuel Parkes & Co Ltd v Cocker Brothers Ltd* (1929) 46 RPC 241 (HC) applied.

2 The proposed amendments sought to incorporate "matter not in substance disclosed in the specification before the amendment" and accordingly could not be made under s 40(1) of the Patents Act 1953. In addition, the amendments related only to the question of novelty under s 41(1)(e) of the Act and could not affect the finding on obviousness under s 41(1)(f) of the Act (see para [71]).

Appeals dismissed.

Observation: Except in special circumstances, it is not appropriate to support an existing patent and then in subsequent amendment proceedings seek to support an amended version of the patent and introduce new evidence directed to issues already decided. In general the patentee should notify any amendments sought before trial and should present supporting evidence before the validity of the patent is ruled upon. It will be for the Court to direct whether the amendment is dealt with prior to, or at, trial (see paras [29], [33], [34]).

Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] RPC 59 (CA), *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] 1 FSR 561 and *Procter & Gamble Co v Peaudouce (UK) Ltd* [1989] 1 FSR 614 (CA) applied.

Other cases mentioned in judgment

Beecham Group Ltd v Bristol-Myers Co [1981] 1 NZLR 600 (CA).
Beecham Group Ltd v Bristol-Myers Co (No 2) [1980] 1 NZLR 192.
Catnic Components Ltd v Hill & Smith Ltd [1982] RPC 183 (HL).
General Tire & Rubber Co v Firestone Tyre and Rubber Co Ltd [1972] RPC 457 (CA).

Application

These were appeals: (CA 160/98) by Ancare New Zealand Ltd from the judgment of Morris J (High Court, Auckland, CP 480/97, 19 June 1998) granting the application by Novartis New Zealand Ltd and Cyanamid of NZ Ltd under s 41 of the Patents Act 1953 for the revocation of a patent held by Ancare, with Cyanamid being the only respondent in the appeal; (CA 170/98) by Cyanamid from Morris J's refusal to revoke the patent on other grounds; and (CA 270/99) by Ancare from the judgment of Morris J (High Court, Auckland, CP 480/97, 10 November 1999) in which the respondents were Cyanamid and Nufarm Ltd, following the remission of the issue of amendment to the High Court by the Court of Appeal (CA 160/98 & CA 170/98, 28 July 1999) refusing an application by Ancare to amend the patent under s 39 of the Patents Act 1953.

Brian Henry and *Kadri Elcoat* for Ancare New Zealand Ltd.

Clive Elliott and *Timothy Jackson* for Cyanamid of NZ Ltd and Nufarm Ltd.

Cur adv vult

The judgment of the Court was delivered by

GAULT J. **[1]** Novartis New Zealand Ltd and Cyanamid of NZ Ltd applied to the High Court for revocation of New Zealand Patent no 237086 in the name of Ancare New Zealand Ltd. Prior to the trial, we were told, application had been made under s 39 of the Patents Act 1953 on behalf of the patentee to amend the patent specification. The statement of defence sought by way of counterclaim:

> "(b) In the event of this Honourable Court determining that the patent is invalid the defendant seeks an order allowing the specification to be amended under s 39 instead of revoking this patent."

No proposed amendments were there particularised but those sought in the separate amendment application presumably were contemplated.

[2] In a judgment delivered on 19 June 1998 (High Court, Auckland, CP 480/97) Morris J held the patent invalid on grounds of lack of novelty or prior publication (s 41(1)(e)) and obviousness (s 41(1)(f)). The Judge recorded that he did not hear argument on the question of amendment. He made an order for revocation but directed that it not take effect in the event that amendment was pursued. After judgment a new application for amendment was made. The amendments proposed were very much more extensive than those we understand to have been proposed prior to trial. The new proposed amendments were formulated to meet the grounds of invalidity upheld in the judgment.

[3] The patentee appealed to this Court. In a brief judgment delivered on 28 July 1999 (CA 160/98 & CA 170/98) we ordered that the amendment application be ruled upon in the High Court before the validity issues were dealt with on appeal.

[4] Morris J, after hearing further evidence and argument, delivered a further judgment on 10 November 1999 (High Court, Auckland, CP 480/97). He refused the amendments sought because they would not overcome the invalidity he had found on the ground of obviousness. He did indicate that, had the amendments overcome obviousness, he would have been disposed to exercise his discretion in favour of the patentee and allow them.

[5] There are now before the Court the appeals by the patentee against both judgments of Morris J. Cyanamid of NZ Ltd supports both judgments and further contends that the patent should be held invalid and the amendments refused on additional grounds. Nufarm Ltd supports the second judgment as an opponent to the application for amendment.

New Zealand Patent no 237086

[6] The patent in question was finally granted on 9 May 1994 though it is dated 11 February 1992 which is the date of the filing of the complete specification (s 30). The earliest priority date of the claims, the date of the filing of the application accompanied by a provisional specification (s 11(2)), was 12 February 1991. That is the crucial date for present purposes.

[7] The complete specification gives as the title for the invention "Anthelmintic Formulations". Under the heading "Field" the description begins with a general statement that the invention relates to:

> ". . . pharmaceutical compositions for the treatment of helminthiasis in warm-blooded animals, more particularly cattle, sheep, goats, and other domesticated herbivores."

[8] There is next, under the heading "Background", a brief statement of the then state of knowledge (prior art) and the problem addressed by the invention. This reads:

> "Helminthiasis is a widely occurring disease in farmed animals. It commonly causes clinical disease and has significant adverse economic effects on farming economies when present at subclinical levels. Over the past twenty-five years a number of initially successful anthelmintic agents, with relatively specific effects on the metabolism of smaller or larger groups of endoparasites have been discovered, trialled, and used successfully to control helminthiasis on farms. Various groups of compounds have a greater or lesser spectrum of activity – that is to say they are able to destroy a wider or smaller range of parasite. For example, the widely used 'ivermectin' is active against parasitic roundworms and also against some ectoparasites, yet it is inactive against tapeworms because of a difference in their biochemical constitution. 'Triclabendazole' is active only against the liver fluke *Fasciola hepatica*.
>
> Unfortunately, resistance to the effects of particular compounds or related families has usually developed with time, after repeated use of the same compound, and has become one of the major problems in the use of these anthelmintic agents. In fact, the growth of drench resistance seems to be overtaking the ability of scientists to develop new drenches. The spread of 'sheep measles' (cysts of the *Taenia ovis* species of tapeworm) is one such problem.
>
> There is a need, therefore, for alternative anthelmintic formulations having the breadth of activity of the benzimidazole drugs (for example) but which slows the advancement of drench resistance."

Helminthiasis is a generic term encompassing the effects of parasitic worms including roundworms (nematodes), tapeworms (cestodes), and flukes (trematodes). The derivative term anthelmintic describes agents for treating worms.

[9] The "Object" of the invention is stated as "to provide novel pharmaceutical compositions having anthelmintic activity." That is followed by the statement of invention:

> "In one aspect the invention provides a veterinary liquid anthelmintic composition suitable for administration to farm animals including a liquid carrier and an effective amount of the anthelmintic praziquantel together with an effective amount or amounts of at least one other anthelmintic selected from the group comprising the avermectins; milbemycins; levamisole; tetramisole; or a benzimidazole chosen from the group comprising mebendazole, fenbendazole, oxfendazole, albendazole, cambendazole, parbendazole, oxibendazole, flubendazole or cyclobendazole.
>
> Praziquantel (*2(Cyclohexylcarbonyl)) -1,2,3,6,7, -11b -hexahydro -4H -pyrazino[2,1-a]isoquinolin-4-one*) has for many years been used to control cestode infestations and schistosomiasis in humans. The surprising discovery that the efficacy of praziquantel can be enhanced in domesticated animals by simultaneous administration with other anthelmintics (as listed above) has been exploited in the present invention, which offers improved efficacy in the control of cestodes, together with simultaneous control of nematode infestations."

[10] As is customary, the first of these paragraphs is carried into claim 1. The second paragraph has been the subject of considerable focus and was sought to be amended in the application for amendment filed before trial, at least by deletion of the second sentence. That was referred to during the hearing as the synergy statement.

[11] The specification continues with statements of preferred embodiments of the invention, including these paragraphs:

> "When administered to sheep or lambs we prefer to administer the composition as a drench having an effective amount of praziquantel in the range of 2 to 7.5 mg/kg of body weight, and more preferably about 4 mg/kg of body weight of sheep. For lambs the dose rate of praziquantel can be reduced to about 2 mg/kg of body weight.
>
> Since praziquantel is a relatively insoluble material, we have devised formulations for administration in the form of drenches and examples are included in this specification.
>
> We have previously found that combining benzimidazole drenches with levamisole drenches results in an unstable product due to the different pH values needed to maintain the stability of the individual products. Mixtures of levamisole as the hydrochloride together with praziquantel are stable, provided that the pH of the mixture is lower than approximately 4."

[12] The reference to previous stability problems in combinations of benzimidazole and levamisole drenches relates to an earlier Ancare patent for a combination drench product sold as "Arrest".

[13] The specification next has the heading "General Formulation" under which it is stated:

> "A typical formula for this invention would include the following active ingredients:

praziquantel	active in a range of activity from 0.5 – 15% w/v
AND	
benzimidazole	active in a range of activity from 1 – 15% w/v
OR	
levamisole	active in a range of activity from 1 – 10% w/v
OR	

. . .

and one or more of the following ingredients to enhance stability and characteristics of the composition:

viscosity agents
surfactants
sanitizers
acidifiers
stabilizers".

[14] Thereafter there are given six "Examples" described in terms indicating that only example 1 had been actually formulated. That is the praziquantel and levamisole HCl drench. There are then described "Trials" commencing with these general statements directed to prior knowledge of effective dose rates:

> "The formulation of Example 1 has been shown in a series of New Zealand trials to be highly effective in controlling benzimidazole resistant roundworms and tapeworms in sheep.
>
> While levamisole has been well researched for the control of helminths in sheep, there historically has been little information on praziquantel in the ovine. Thomas & Gonnert Research in Veterinary Science (1978) 24, 20 report a high efficacy in the control of Moniezia spp at a dose of 2.5 mg/kg, while other studies against liver tapeworm (Stilesia hepatica) demonstrated efficacy at 15 mg/kg.
>
> A recent study by C Bauer Veterinary Record (1990) 127, 353 – 354 demonstrated an adequate efficacy against Moniezia expensa in lambs at a dose of 3.75 mg/kg. Based on this study a praziquantel dose of 3.75 mg/kg was chosen."

[15] The results of one of the recorded trials indicate lower comparative efficacy against tapeworms of albendazole at the same dosage. We were told this indicated resistance in the animals involved.

[16] After the description of the trials the specification has the heading "Variations" under which this paragraph appears:

> "A range of compositions have been described suitable for the treatment of prevention of helminthiasis in sheep and goats. The trials show dose rates of 3.75 mg/kg of praziquantel and 8 mg/kg of levamisole. We have discovered that the dose rate of the formulation of Example 1 can be reduced, thereby reducing the dose rate of praziquantel to about 2 mg/kg whilst preventing sheep measles in lambs. Preferred dose rates for lambs and sheep are in the range of 2 – 7.5 mg/kg of live body weight of praziquantel, giving a comparable range of levamisole of 4 – 16 mg/kg of live body weight."

[17] The specification of the patent as granted has 21 claims. The broadest, claim 1, reads:

> "A veterinary liquid anthelmintic composition suitable for administration to farm animals including a liquid carrier and an effective amount of the

anthelmintic praziquantel together with an effective amount or amounts of at least one other anthelmintic selected from the group comprising the avermectins; milbemycins; levamisole; tetramisole; or a benzimidazole chosen from the group comprising mebendazole, fenbendazole, oxfendazole, albendazole, cambendazole, parbendazole, oxibendazole, flubendazole or cyclobendazole."

[18] The next five claims introduce a series of limitations on claim 1. Claim 6 narrows the invention claimed in claim 1 to a drench and specifies the liquid carrier as non-toxic. The subsequent claims incorporate specific elements in the drench as claimed in claim 6. The last four claims are of methods of treating helminthiasis in animals with drenches as claimed in earlier claims.

[19] In his first judgment Morris J held that the invention lacked novelty in that it was disclosed by the prior publication on 19 November 1975 of New Zealand Patent no 176193. This, which was referred to as the Bayer patent, disclosed and claimed a group of isoquinoline compounds of which praziquantel is one.

[20] The ground of invalidity through lack of novelty is that provided in s 41(1)(e) which reads:

> **41. Revocation of patent by Court** – (1) . . .
> (e) That the invention, so far as claimed in any claim of the complete specification, is not new having regard to what was known or used before the priority date of the claim in New Zealand.

The Bayer patent

[21] There was no challenge to the Bayer patent as part of the prior art. The Judge considered the disclosure in the complete specification of that patent against the Ancare invention without separately focusing on each of the Ancare claims. He found what he was satisfied was disclosure of the elements of the Ancare invention.

[22] The group of isoquinolines disclosed and claimed in the Bayer patent, as Mr Henry emphasised, encompasses some 500 separate compounds. For that reason the specification is daunting to non-chemists. Necessarily the disclosure is technical and the instructions for preparing the compounds are lengthy. But it is nonetheless clear (and not in dispute) that the specification discloses and claims praziquantel as a new compound. The patent is acknowledged as having protected praziquantel until its expiry in December 1990. The specification describes the compounds as "effective as anthelmintics and have an especially wide spectrum of activity against cestodes and trematodes" and "can be used as pharmaceuticals in human and/or veterinary medicine". It is said further that the compounds can be used for "combating cestodes or trematodes [in] ruminants, such as cows, sheep and goats . . . as such or admixed with pharmaceutically acceptable inert carriers." The forms of administration are described as including "aqueous suspensions, injectable solutions, emulsions and suspensions, elixirs, syrups and pastes" which it is said "can be prepared in known manner, for example, by the addition of the active materials to solvents and/or carrier materials . . .". It is also said that administration preferably takes place orally. There is this passage at p 38 which Morris J quoted at p 28:

> "The compounds (I) can also be present in the formulations in admixture with other active materials. Thus, for the achievement of a broader spectrum of activity, it can be useful to add an active material which acts against nematodes, for example thiabendazol [2-(4-thiazolyl) –

benzimidazole/ or piperazine (or a piperazine derivative, such as N-methyl-piperazine)."

Thiabendazol is not one of the benzimidazoles specified in claim 1 of the Ancare patent.

[23] The Bayer patent specification describes tests carried out for anthelmintic action on a number of the new compounds, including praziquantel, against comparative preparations one of which is niclosamide. None of those tests was for cestode reduction in farm animals.

[24] Sixty preparation examples are described. Example 56 describes the mixture of a syrup containing as the active praziquantel for combating cestodes in human medicine, and example 58 describes an injection liquid for human and veterinary medicine of which the active is praziquantel.

[25] The claims include claim 32 for an anthelmintic comprising an effective dose of at least one of the new compounds in admixture with a liquid or semi-liquid pharmaceutical diluent or carrier, and claim 33 for a method of treating helminthiasis in veterinary medicine by administering an effective dose of at least one of the new compounds.

[26] It was submitted that the strict test for lack of novelty – that the claimed invention would be infringed by carrying out the teaching of the prior publication (*General Tire & Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457 at p 485) – is not met by the disclosure in the Bayer patent. Certainly it does not go so far as to expressly describe the commercial embodiment of Ancare's invention being a sheep drench comprising effective amounts of praziquantel and levamisole in a liquid carrier. But in so far as the invention is more broadly claimed the matter is not so clear. That involves the question of what the broad inclusive terms of the prior disclosure would convey to the skilled addressee.

[27] However, because the patentee sought amendments to the patent to overcome the lack of novelty found by the Judge, because Mr Henry affirmed that it is the amended patent he seeks to uphold and because the Judge rested his second judgment on obviousness, it is unnecessary for us to reach any final view on novelty.

The amendment procedure

[28] Before dealing with obviousness it is necessary to say something about the procedure followed in this case which resulted in Ancare supporting the validity of the patent first in unamended form and subsequently in the form as it was proposed to be amended. It resulted also in the Judge in his second judgment, having heard further evidence and after ruling on the validity of the patent, stating at p 6:

> "I accept Ancare's present application must be considered in the light of the totality of the evidence which is now before me. It follows I must alter my earlier expressed views if the evidence satisfies me such would be the proper course to take."

[29] It seems quite inconsistent with the fundamental requirement that a patentee must clearly define the invention and with the need for competitors to know the scope of the monopoly into which they cannot trespass that a patentee can engineer a situation in which two versions of the patent are supported and a Court, after finding invalidity, is required to consider further evidence directed to an issue already decided.

[30] Mr Henry argued that the course followed in this case is contemplated in the wording of s 39(1) which provides that ". . . if in any such proceedings for revocation the Court decides that the patent is invalid, the Court may allow the specification to be amended under this section instead of revoking the patent." That is the same wording as appeared in s 30(1) of the Patents Act 1949 (UK), but no case was cited to us in which that has been construed as permitting the formulation of amendments after a finding of invalidity and a further hearing with new evidence and argument that the earlier decision should be revisited.

[31] The practice under the 1949 English Act appears to have been that where amendments were sought in proceedings for infringement or revocation directions were sought and given on whether the amendment application should be ruled upon prior to or at the trial. Indeed Blanco White in *Patents for Inventions* (4th ed, 1974) para 7.202 n 46 suggests that after judgment there may not be a proceeding in which to seek amendment.

[32] The matter was complicated in the present case by the fact that there was an application for amendment made before trial of the revocation proceeding and the Judge was persuaded to defer consideration of that until after trial and then, after trial, a new and more extensive application for amendment was made.

[33] We think s 39(1) and the English equivalent, which are directed to applications to the Court for amendment in proceedings for infringement or revocation, are not to be construed as permitting patentees the opportunity to support the validity of patents in alternative versions. In *Windsurfing International Inc v Tabur Marine (Great Britain) Ltd* [1985] RPC 59 at pp 81 – 82 the Court of Appeal, after upholding the first instance decision of invalidity, said:

> "Therefore, it is argued, the plaintiffs ought to be given the opportunity to amend by restricting their claims specifically to surfboards and to the specific claim 7 embodiment, the judge having wrongly concluded that there was no scope for such an amendment on a wrong principle. We are unable to accept this.
>
> In the first place, as Mr Young has pointed out, it was for the plaintiffs, if they wished to support their claim to monopoly on some alternative basis, to raise the point and adduce the appropriate evidence for that purpose at the trial. In fact, however, no-one, from first to last, advanced or considered the specialised qualities of a surfboard as an inventive concept and the suggestion that there should be an adjournment for this now to be raised and investigated as the basis for the claim to monopoly involves, in effect, a fresh trial, the recalling of most, if not all, of the most important witnesses, and a considerable degree of recapitulation of the evidence as well as the calling of fresh evidence on an issue never previously suggested either in the specification or in the pleadings. We would require considerable persuasion that the imposition upon a successful defendant of such a manifestly inconvenient and oppressive course would be a proper exercise of discretion even in an otherwise strong case."

[34] There may be special circumstances in which amendment can be entertained after judgment – as where the patent is held invalid in part and amendment is required to excise invalid parts – but in general the patentee should notify any amendments sought before trial (with the appropriate advertisement for opposition) and should present supporting evidence before validity is ruled upon. It will be for the Court to direct under R 725ZD of the

High Court Rules whether the amendment will be dealt with prior to, or at the trial of the proceeding. That accords with the views expressed in the cases cited in the notes to the rule in *McGechan on Procedure*.

[35] Delay without reasonable grounds in seeking amendment, and assertion of the monopoly unamended with knowledge of grounds of invalidity have long been reasons for refusing to exercise the discretion to permit amendments – see the authorities reviewed by Aldous J in *Smith Kline & French Laboratories Ltd v Evans Medical Ltd* [1989] 1 FSR 561.

[36] In *Procter & Gamble Co v Peaudouce (UK) Ltd* [1989] 1 FSR 614 in the Court of Appeal, Fox LJ, with reference to an application for amendment, said at pp 615 – 616 (with the agreement of the other members of the Court):

> "In fact no question of any amendment or any application for such relief in the alternative was raised until 31 July of this year in consequence of the decision of the court that the patent was ambiguous in its terms. If it had been, any necessary evidence could have been investigated before the judge and the question of whether the amendment was proper could have been determined by the end of July. As it is, if we now give leave to proceed with an application for amendment, the other side are left in the position that probably very extensive further litigation, quite apart from any proceedings in the House of Lords, will then be necessary with the result that this patent, which at the moment is held to be invalid, may by reason of suspension of any order for revocation pending investigation of the validity of the application to amend, be continued for a further lengthy period.
>
> It is admittedly a matter for the discretion of the court whether to allow the application to be made. Speaking for myself, I am of the opinion this is not an appropriate case to give such leave. I think it is altogether too late and I think that it is unfair to the other party that the possibility of disputes in this litigation should be continued for so lengthy a period as might be necessary, if an application for amendment were to be made. The patentee had ample opportunity to raise the matter in the lengthy litigation which has taken place and which has been on foot now for some five and a half years. Looking at the whole matter, in the exercise of our discretion, I would, for the reasons which I have indicated, refuse the application."

[37] That does not exclude the possibility of a patentee, acting reasonably, seeking to resist the challenge to validity without amendment and, upon delivery of an adverse decision, then seeking and being allowed amendment. But the risks inherent in that course, if the amendments can reasonably have been notified prior to trial, are plain enough.

[38] In the present case the course followed may have resulted in little prejudice, although the amendment hearing after the trial has had the effect of prolonging the monopoly when others, by their participation in the proceedings, have signalled their wish to enter the market.

[39] We think it would have been better if the patentee had notified all amendments sought to distinguish the cited prior art before the first hearing and for the issue of validity to have been determined in light of the ruling on the amendments.

Obviousness

[40] In this Court Mr Henry made it clear that his ultimate objective was to have the patent in amended form held valid. He accepted, however, that the

amendments were proposed to overcome the finding of lack of novelty and that he could not contend that they were of assistance on the ground of obviousness. That was because he maintained that the amendments merely clarified aspects of the invention that would have been apparent to the skilled addressee of the specification in any event. Accordingly, if the invention as claimed was, as the Judge held, obvious to a skilled addressee, it would make no difference to spell out matters that would be apparent to such a person.

[41] This ground of invalidity is provided in s 41(1)(f) as follows:

> **41. Revocation of patent by Court –** (1) . . .
> (f) That the invention, so far as claimed in any claim of the complete specification, is obvious and does not involve any inventive step having regard to what was known or used before the priority date of the claim in New Zealand.

[42] It is to be noted that the same words are used as in s 41(1)(e) in identifying the prior art against which the matter is tested: "having regard to what was known or used before the priority date of the claim in New Zealand". That has not always led to acceptance of the same documentary material being taken into consideration under the two subsections. Morris J adopted a narrower approach when considering obviousness, as did Barker J in *Beecham Group Ltd v Bristol-Myers Co (No 2)* [1980] 1 NZLR 192 at p 253 though it was not mentioned in the judgment on appeal: [1981] 1 NZLR 600. Morris J found the ground of invalidity made out even on that approach. It is not the approach preferred in the *Windsurfing International* case. Like Morris J, we are able to reach a clear view without reference to documents the availability of which might be contentious and so we do not need to reach a final view on just what documents should be regarded as "known" for the test of obviousness.

[43] That aside, the test is well established. It postulates a person (or, where appropriate, a team) skilled in the field but not inventive, invested with the common general knowledge available in the field at the priority date, presented with the prior knowledge or prior use relied upon. Prior documents may be looked at together if that is what the skilled person or team would do. It asks whether to that person or team the alleged inventive step would be obvious and would be recognised, without bringing to bear any inventiveness, as something that could be done or is at least worth trying. That is a question of fact. If any embodiment within the scope of the claim is obvious the claim is invalid. These propositions are helpfully expanded upon in the recent English cases which are still applicable though under the 1977 Act; see the *Windsurfing International* case, *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195 at p 211, and *Mölnlycke AB v Procter & Gamble Ltd* [1994] RPC 49 at p 112.

[44] As Mr Henry emphasised, the element of inventiveness necessary to resist attack is not high. He referred to the need only for a "scintilla" of invention (*Samuel Parkes & Co Ltd v Cocker Brothers Ltd* (1929) 46 RPC 241 at p 248, but see *Mölnlycke AB v Procter & Gamble Ltd* at p 112). He referred also to the need to avoid the influence of hindsight and stressed the secondary consideration indicative of invention – the commercial success of the patented invention.

[45] Morris J in his first judgment formulated the relevant test by reference to leading judgments in terms that were not criticised in the argument in this Court. He adopted the four-step approach set out in the *Windsurfing International* judgment at pp 73 – 74:

> "There are, we think, four steps which require to be taken in answering the jury question. The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being 'known or used' and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention."

[46] In following these steps Morris J did not expressly identify the inventive concept in the Ancare patent. He merely referred back to his findings on the scope of the claims which he had earlier made when dealing with an argument on their correct construction. That argument was repeated in this Court. It was that giving the purposive construction directed in *Catnic Components Ltd v Hill & Smith Ltd* [1982] RPC 183 at p 243 per Lord Diplock, the patent specification must be understood when describing and claiming a veterinary composition (or drench) suitable for administration to farm animals as necessarily including the four attributes:

(i) adequate shelf life: minimum two years;
(ii) capable of storage at ambient temperature, ie in a shed for at least one full season;
(iii) ready for use throughout its shelf life; and
(iv) easily mass administered to farm animals.

Morris J did not accept that and neither do we. The words "suitable for administration to farm animals" do not connote commercial viability but simply qualify the suitability of the composition in use. The expression is not the same as "suitable for use on the farm". In this respect it can be noted that the words "suitable for administration to farm animals" were inserted by way of amendment at the examination stage of the patent application in response to an objection based on s 17(1)(c) of the Act (as it then read) which precluded patents for mere mixtures of known ingredients capable of being used as food or medicines and which the applicant argued were directed only to foods and medicines for humans. Morris J rightly construed the claims as extending to all veterinary anthelmintic compositions suitable for administration to farm animals and comprising a liquid carrier and effective amounts of praziquantel and at least one other anthelmintic within the designated groups. He identified three essential integers as a liquid carrier, praziquantel and another of the specified class of anthelmintics.

[47] Some further assistance is available in ascertaining how the Judge identified the inventive concept in that part of his first judgment in which he found against the ground of revocation that the patent did not claim an invention within the meaning of the Act (s 41(1)(d)) – a finding that is not easily reconciled with his finding that the patent was invalid for obviousness. In that part of the judgment he referred to "the method of using praziquantel in this manner (the mixing of it with levamisole in a liquid form)". This suggests he saw the inventive concept as the combining of the anthelmintic actives

praziquantel and one of the others of the specified class in a liquid composition suitable for administration to farm animals. That is close to the breakthrough the inventor Mr Harvey claimed in his evidence to have made. In his first brief of evidence he said:

> "40. The mixing of two actives is a feature of the invention described in the patent but the concept of combining anthelmintics is not in itself novel. Praziquantel was known to be an extremely difficult compound to work with. It was not readily soluble and was not an obvious choice for combining with other anthelmintics. The invention was seeing that this could be done and then working the active Praziquantel into a suitable liquid formulation with the other actives while each retained their spectrum of activity."

[48] It happened that Ancare had a product already on the market under the name Levitape which was a liquid drench comprising essentially levamisole for treating roundworm and niclosamide for treating tapeworm in a liquid carrier. That was also the subject of a patent. Difficulties had been encountered in formulating a composition combining these two actives. Niclosamide was found to be unstable when mixed with water and even if formulated in water-free liquids would thicken if contaminated with water such as when farmers washed their drench guns. After the Bayer patent expired Mr Harvey instructed his formulator to try substituting praziquantel for niclosamide in the Levitape formulation. This proved entirely satisfactory and was the foundation for the patent now in issue and for the commercial product sold by Ancare. The manner in which the invention was arrived at was said to have been a "punt" or flash of inspiration not inconsistent with invention. Certainly that does not automatically indicate the invention would have been obvious to the notional skilled person or team with which the law is concerned.

[49] Morris J, therefore, may be taken as having proceeded on the basis that the inventive concept is that of formulating praziquantel known to be active against tapeworm and one of the other specified compounds known to be effective against roundworm in a liquid composition suitable for administration to animals.

[50] The Judge then proceeded to identify relevant common general knowledge. His conclusions were:

> ". . . there was nothing new in the concept of combining two actives in one anthelmintic composition or drench. I have earlier detailed the development of these in New Zealand. By 1991 there were a number of combination drenches produced, which accounted for a good percentage of the anti-parasitical market eg Leviben, Milsen, Levitape.
>
> The notional addressee would have been aware not only of the existence and development of combination anthelmintic composition and drenches but also of their make-up, their claimed effectiveness and no doubt their actual effectiveness. He would therefore have been aware a number were designed to treat both roundworm and tapeworm and claimed to do so. He would also have been aware levamisole, the BZs and niclosamide were actives used in such products, although he would not have known the specific details of their formulation. He would have been aware of the water difficulties which faced niclosamide and he would have been aware of the drawbacks of many of the other existing drenches and their actives, a number of which were discussed by Professor Charleston.

. . . the notional addressee would have been aware of the following:

(i) there was no scientific proof tapeworms in lambs caused reduced growth or disease but farmers and veterinarians were of the view tapeworms in lambs should be eradicated;

(ii) a market for anti-tapeworm and anti-roundworm products had been recognised and there was competition for this market (hence the various products and the continual manufacturing of new and allegedly improved products);

(iii) there was growing resistance of roundworms to BZs. I do not accept the notional addressee would have been aware the tapeworm had developed a resistance to BZs as claimed by Mr Harvey.

. . . the qualities and characteristics of levamisole would have been well known and appreciated by the notional addressee. Specifically, he would have known it was soluble in water and was a roundworm active. He would have known it was already on the market in anthelmintic products in 1991 as such. . . .

The evidence establishes prior to 1991 praziquantel had been widely and effectively used as a tapeworm active in the hydatids control problem in New Zealand. It had been widely used for treatment of tapeworm in pet animals eg dogs and cats. It had been produced as a tablet on its own and in combination with other actives eg 'drontal +' which contained praziquantel, febental, pyrantal and palmoate. It had also been produced as a liquid injectable solution" (pp 41 – 43).

[51] Next the Judge determined the published material "known" in New Zealand before the priority date which the skilled person or team, armed with the relevant common general knowledge, would consider. He included the Bayer patent, of which he said at pp 44 – 45:

". . . this patent clearly teaches the use to which praziquantel can be put. It teaches praziquantel can be combined with other actives which, in 1991, would include the early BZs and levamisole. It also teaches praziquantel can take the form of liquid formulations including aqueous suspensions and it teaches it can be used to treat tapeworm in farm animals and specifically in sheep."

He referred to three published articles which he briefly summarised as follows:

"**The Andrews and Thomas article:**

This article was found by both Mr Harvey and Professor Charleston in the course of their searches. It is extremely thorough and covers almost every relevant aspect of praziquantel. Particularly, it establishes praziquantel was effective against tapeworm in sheep without any known side effects. It is noteworthy because it contains a very detailed and practical source of references on investigating the use of praziquantel. I am satisfied it would have been found by a diligent researcher in 1991 and forms part of the prior art available for consideration.

The Bauer article:

It is accepted this properly forms part of the prior art available. The article discusses the comparative efficacy of praziquantel, albendazole, febantal and oxfendazole against tapeworm. It purports to show praziquantel is

effective in treating tapeworm in sheep and it can be administered in a liquid suspension and noteworthy, in a relatively low dose. It also teaches all four of the substances (ie praziquantel, albendazole, febantal and oxfendazole) were of a similar efficacy for the treatment of tapeworm infections in sheep.

The article titled 'Helminthologia':

This article is accepted as being available as prior art. It relates to the use of praziquantel and albendazole in the treatment of cysticeri in cattle. It shows praziquantel could be combined with other active substances in a combination drench and could be administered orally in a drench suspension to farm animals (calves)" (pp 45 – 46).

[52] Interestingly the Judge did not refer to what was "used" before the priority date. That would have included the Levitape composition of levamisole and niclosamide formulated and sold by Ancare.

[53] The Judge's answer to the third question posed in the *Windsurfing International* test – the difference between what was known and used and the claimed inventive concept – was that the combination of levamisole and praziquantel in liquid form for use as an anthelmintic composition or drench had not been manufactured. He then posed the fourth, and essential question at p 48:

> ". . . would a combination of levamisole and praziquantel in liquid form as an anthelmintic composition or drench have been obvious to the hypothetical addressee in 1991 when seeking, as Mr Harvey was, a broad spectrum product capable of dealing with both roundworm and tapeworm?"

[54] The way this question was framed is at the heart of the present appeal and will be considered later in this judgment. Meantime, to complete the narrative, the Judge reviewed the evidence he had heard from the expert witnesses and reached the conclusion that the relevant skilled team considering whether a drench aimed at both roundworm and tapeworm could be produced would have selected levamisole as the obvious choice of active to deal with roundworm and would have considered praziquantel as a logical active to deal with tapeworm. He said at p 55:

> "I am satisfied the hypothetical addressee or team would have seen the problem worth treating and provided it could be formulated the use of praziquantel in a composition or drench with levamisole would have been worth putting together and giving a try."

He found broad support for this in the evidence.

[55] The Judge then turned to the evidence directed to formulation. There was a conflict of expert testimony. He preferred that of Dr Rowe for reasons he set out and concluded that it would have been obvious to formulate praziquantel and levamisole which could have been carried out without difficulty. It may fairly be said that had he taken into account that there was already in use in New Zealand before the priority date a formulation combining levamisole with the insoluble niclosamide anthelmintic in a liquid carrier he might have reached his conclusion even more easily. Further, he could have referred to the description in the specification of the patent in issue which treats formulation as a matter left to the addressee (para [13]).

[56] Morris J ended his careful treatment of obviousness in his first judgment with mention that he had not overlooked the commercial success of the Ancare product covered by the patent and had been careful to exclude from his consideration of the issue the manner in which Mr Harvey actually arrived at his composition.

The principal argument on the appeal

[57] Mr Henry's principal argument was that the Judge posed for the notional skilled person or team the wrong question and, in doing so, avoided focus on the real inventiveness. The argument bore considerable similarity to that advanced unsuccessfully by counsel for the patentees in the *Windsurfing International* and *Hallen Co v Brabantia* cases. It was submitted that the Judge formulated his question for obviousness too far down the path of invention. By asking, as the Judge did, if the patented composition would have been obvious to a skilled person "seeking, as Mr Harvey was, a broad spectrum product capable of dealing with both roundworm and tapeworm", the inventiveness in determining to seek such a product was excluded. The difficulty with this argument is that it asserts that the skilled person or team would not seek to do exactly what Ancare itself was doing before the priority date in marketing a broad-spectrum combination product for the treatment of both roundworm and tapeworm – the Levitape product. Also it is not consistent with how the invention is described in the patent.

[58] Mr Henry developed his argument as follows. Defining the problem to be solved may be an inventive step. Therefore, for an alleged invention to be obvious both the question and the answer must be arrived at by the skilled person or team without any inventive step. The initial question – would a skilled person identify the problem? – must be answered from the common general knowledge in the field and without working back from the invention claimed. In the present case the skilled team would not seek a combination roundworm and tapeworm anthelmintic for farm animals, and certainly not one incorporating praziquantel because the scientific teaching at the relevant time was that tapeworm did not affect the growth rate of lambs and so presented no economic need for their treatment in the first few weeks of their lives before natural immunity built up. Further, some of the known anthelmintics marketed to treat roundworm were claimed also to treat tapeworm – as was borne out by the tests described in the Bauer article showing albendazole at least as effective against tapeworm as praziquantel. The skilled team is required to ignore the fact that there is a market demand for a combination roundworm and tapeworm anthelmintic and to focus on the state of scientific knowledge. Therefore, the skilled team would be turned away from seeking any tapeworm drench, and even if that was sought, would select albendazole as the active and not praziquantel. To contemplate the use of praziquantel the skilled team would have to challenge the prevailing authoritative scientific opinion that treatment of tapeworm was unnecessary and to have rejected the obvious active albendazole without knowing what Mr Harvey believed: that resistance had built up to the benzimidazoles. There was thus invention in recognising that the scientific teaching was wrong and that there had developed a resistance to the obvious choice of product so that alternatives were needed.

[59] Morris J did address this argument in his first judgment in this passage at p 54:

> "As I have endeavoured to show it was a substantial market, growing as companies continued to [compete] for a share thereof. As I have earlier

> stated, anthelmintic productions had, prior to 1990, been aimed at both worms even when scientific evidence was lacking as to the ill effects of tapeworms on lambs. On the material before me I cannot conceive a team being asked the question I have previously formulated saying: 'We will have none of this, you are wasting our time'. I am satisfied the hypothetical addressee would have taken time to consider whether a product, as asked of him, namely a drench aimed at both roundworm and tapeworm could be produced. If this were not the case it would mean the hypothetical addressee being asked to formulate a product within his or their expertise, could veto its production taking into account his personal views on such matters as the economy, sales or the size of the market in respect of which others were the experts."

[60] Mr Henry's argument must be rejected for a number of reasons. First, the patent specification does not identify and describe the invention in terms consistent with the inventive step being the discovery (contrary to scientific opinion) of economic benefit in the treatment of tapeworm in farm animals or the discovery of resistance having developed to the benzimidazoles as treatments for tapeworm. Rather the specification recites both the economic effects on farming economies of helminthiasis and the major problem with resistance to particular compounds as part of the prior art in the "Background" section of the specification.

[61] Secondly, the inventor's own evidence does not focus on those discoveries as his invention.

[62] Thirdly, the argument turns the underlying rationale for the grant of patent protection on its head in suggesting that in testing for obviousness what is happening in the market is to be ignored. Patents are granted for real advances in knowledge capable of industrial application. No patent should interfere with what has been done or disclosed before nor with obvious variants of what has been done or disclosed before. To ignore what is being done in the market because it does not accord with scientific opinion would lead to the grant of a patent for what is already in use – or obvious extensions. To have regard to what is known or used as the statute dictates cannot mean only the scientific literature to the exclusion of what is happening in the market. That is not inconsistent with the authorities. They clearly show that it is not helpful to look at the absence of market demand when deciding whether a particular development might be contemplated. But it is essential to have regard to what is known and used.

[63] Fourthly the contention that there was invention in perceiving economic benefits of treating tapeworm in lambs cannot stand with counsel's acceptance that there were farmers who for their own reasons (perhaps misguided) wanted to treat tapeworm. If it is obvious to do something for one purpose it does not become inventive to do it for another. In *Hallen Co v Brabantia* the Court of Appeal put it this way at p 216:

> "True it is that, as the judge found, it was not obvious that coating a self-puller with PTFE would have the dramatic effect that it did in extracting the cork, and indeed that probably without the intervention of the patent in suit such a corkscrew would not have been marketed for many years. However, as he rightly appreciated, these were in law irrelevant considerations. The dramatic improvement in extraction was for the plaintiffs a golden bonus; but it is common ground that an added benefit,

however great, will not found a valid patent if the claimed innovation is obvious for another purpose."

[64] Just what is the correct question must depend on the circumstances of the particular case. It would be a very different question to test the obviousness of the first mousetrap from that for just another mousetrap. In the present case the existence of other combination drenches on the market before the priority date precludes any question framed to test whether the skilled team would consider producing such a combination drench. That is not part of the path of invention.

[65] In the *Windsurfing International* case the Court of Appeal, after considering the argument that the skilled man would merely have dismissed the prior publication without ever reaching the point of considering how the disclosure might be developed, said at p 74:

> "It may well be that nobody in the United Kingdom at that time would have considered that there was a commercial future in this interesting beach novelty, but that is not as we conceive the question which has to be answered. One has, in our judgment, to postulate a person who comes to Darby [the prior publication] knowing of the advantages of a Bermuda rig over a square rig and who is at least sufficiently interested to read the article and consider how the vehicle described would work on the water."

[66] Similarly in this case, what is to be postulated is a skilled person or team at least sufficiently interested to read the cited material eg the Bayer patent, and consider how praziquantel might be formulated in admixture with other materials active against nematodes to achieve a broader spectrum of activity.

[67] Accordingly we find no error in the Judge having framed the question in the circumstances of this case as whether it would be obvious in seeking a product for treating roundworm and tapeworm in farm animals to formulate an anthelmintic composition of the actives praziquantel and levamisole in a liquid carrier. That is consistent with the stated problem in the patent specification: a need for alternative anthelmintic formulations having the breadth of activity of known drugs.

[68] As Mr Henry recognised, should we reject his argument that the Judge asked the wrong initial question – as we have – he faced the difficulty that in answering that question the Judge made findings of fact based on his assessment of the witnesses which will not readily be disturbed on appeal. We have already indicated that the Judge took a narrow approach to the written material appropriate for consideration of obviousness and did not consider the use in New Zealand before the priority date of the Levitape formulation. That was unduly favourable to the patentee. He found on the evidence that the claimed invention was obvious, and we agree.

[69] It is necessary briefly to consider the narrower claims as well as claim 1. The claims immediately dependent on claim 1 (claims 2 – 5) introduce features of the liquid carrier and contain nothing put forward as inventive over claim 1. Claim 6 is the main drench claim. The composition in the form of a drench is not inventive over claim 1 which covers all liquid forms. Claims 7 – 17 introduce limiting features in the formulation of the drench of claim 6 and have not been supported as claiming inventive features over the main claims. Claims 18 – 21 claim methods of treatment by administration of the claimed drenches and include no inventive subject-matter. All claims therefore fall with the main claims, claims 1 and 6.

[70] While Mr Harvey was the first to bring to the market an easy to use effective broad-spectrum drench for treating roundworm and tapeworm incorporating praziquantel, it does not qualify as invention being obvious in the patent law sense in light of what was used and disclosed before the priority date.

[71] We have found, in agreement with the Judge, that the proposed amendments seek to incorporate "matter not in substance disclosed in the specification before the amendment". They, therefore, cannot be made (s 40(1)). In any event we agree with the Judge (and as was conceded) that they would not overcome the invalidity for obviousness. Therefore, we do not reach the discretion whether to allow the amendments should they otherwise fall within the statutory requirements. The Judge indicated that he would have exercised the discretion in favour of the patentee. We did not hear full argument on that point and refrain from expressing any final view. We simply record that we should not be taken as regarding that view as unchallengeable. We note particularly the maintenance of the synergy statement (para [10]) in the specification after the issue of synergy had been raised by the examiner and the offer of its exclusion only after the proceeding was underway and then only in the event that the patent should be invalidated. There was also the inclusion and maintenance of the description of reduced dose rates in the treatment of sheep measles (para [16]) in respect of which informal application for an additional amendment was made before the Judge in the course of the second hearing. That was several years after the challenge to the validity of the patent had been launched.

[72] Ancare's appeals against both judgments are dismissed. It is unnecessary to deal with the cross-appeal by which it was sought to establish invalidity on additional grounds. That too is dismissed.

[73] The respondents are entitled to costs which we fix in this Court (including the 28 July 1999 hearing) at $20,000 together with disbursements including the reasonable travel and accommodation expenses of counsel approved, if necessary, by the Registrar.

[74] Costs in the High Court should be fixed by that Court.

Appeals dismissed.

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