

Privy Council Appeal No. 32 of 2001

Ancare New Zealand Limited

Appellant

v.

**(1) Fort Dodge New Zealand Limited and
(2) Nufarm Limited**

Respondents

FROM

THE COURT OF APPEAL OF NEW ZEALAND

REASONS FOR REPORT OF THE LORDS OF THE JUDICIAL
COMMITTEE OF THE PRIVY COUNCIL, OF THE
6th February 2002, Delivered the 28th February 2002

Present at the hearing:-

Lord Steyn
Lord Hoffmann
Lord Millett
Lord Rodger of Earlsferry
Sir Christopher Slade

[Delivered by Lord Hoffmann]

1. This is an appeal against an order of the Court of Appeal (Gault, Henry and Thomas JJ) [2000] 3 NZLR 299 affirming the decision of Morris J. to revoke the appellants' patent (NZ No 237086) on the ground of obviousness. At the conclusion of the submissions of counsel for the appellants, their Lordships announced that they would humbly advise Her Majesty that the appeal should be dismissed with costs for reasons to be given later. These now follow.

2. As the history is fully stated in the admirably clear judgments of the judge and the Court of Appeal and the only point argued before the Board lay within a very narrow compass, it is unnecessary for their Lordships to give more than a concise account of the relevant facts.

3. Sheep and other animals are susceptible to various parasitic intestinal worms (helminths) which include roundworms (nematodes) and tapeworms (cestodes). The patent in suit is for a

liquid anthelmintic composition suitable for administration to farm animals which contains praziquantel (a compound active against tape worms) and one or more other compounds, such as levamisole or benzimidazole, which are active against roundworms.

4. The judge found that sheep develop a natural immunity to tapeworms after three or four months but not to roundworms, which can attack mature sheep. The received opinion among New Zealand parasitologists at the priority date (12 February 1991) was that round worms were undoubtedly deleterious to the health of the animals but that tape worms, even in young lambs, were not. The latter view was based in particular upon the research of Dr D C Elliott, whose article *Tapeworm (Moniezia expansa) and its effect on sheep production: The evidence reviewed* (1986) 34 NZ Veterinary Journal 61 concluded:

“Since the available evidence indicates that *M. expansa* infections in sheep are generally harmless, no general recommendation to drench against this tapeworm can be made on the basis of any likely benefit to the health or production of the animals.”

5. Dr Elliot noted that a 1983 survey of New Zealand farmer opinion showed that over 70% of farmers and veterinary surgeons nevertheless obstinately believed that tapeworms affected the growth rate of lambs and caused diarrhoea. There was accordingly a demand for anthelmintic preparations which would eradicate tapeworms as well as roundworms. Some benzimidazoles were effective against both worms but most compounds treated either one or the other. Furthermore, it became apparent in the late 80s that the roundworms were developing resistance to the benzimidazoles. The appellants therefore experimented with compositions containing more than one compound so that a single administration could eradicate both worms.

6. In 1988 the appellants marketed a combination product which they called Levitape, consisting of niclosamide (efficacious against tapeworms) and levamisole (for roundworms). It was at first a commercial success but had the disadvantage of becoming unusably viscous if it came into contact with water.

7. The appellants therefore pursued their researches and decided to substitute praziquantel for niclosamide as the active agent for dealing with tapeworms. This presented no formulation problems and led to the patent in suit. The preferred embodiment contains levamisole as the roundworm agent and has been a considerable commercial success. The patent was granted on 12 February 1992.

8. Morris J. held the patent invalid under s 41(1)(f) of the Patents Act 1953:

“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.”

9. He found that praziquantel was a well known compound which had been used to eradicate tapeworms in humans and small animals for a number of years. It had been patented by Bayer but the patent expired while the appellants were engaged in developing their product. It was therefore an obvious choice for the tapeworm element in the composition. Levasimole was well known for treating roundworms and had been so used by the appellants in Levitape. It would therefore have been obvious to anyone familiar with the prior art that if one wanted a combined treatment for tapeworms and roundworms, praziquantel and levasimole were well worth trying.

10. This finding of fact by the judge was affirmed by the Court of Appeal. Mr Henry, who appeared for the appellants, therefore recognised that, in accordance with the normal practice of the Board in relation to concurrent findings of fact, he had little prospect of disturbing them. If the lower courts asked themselves the right question, their conclusions were unassailable. But Mr Henry submitted, as he had to the Court of Appeal, that the judge had erred in principle by wrongly identifying what was claimed to be the inventive step. It was not the idea of combining praziquantel and levasimole to treat tapeworms and roundworms. It was the idea, in the face of scientific hostility to the very notion of treating tapeworms in sheep, of including any tapeworm agent at all. Since the priority date, further researches on the effect of tapeworms on lambs have led to a generally accepted conclusion that they are indeed deleterious to their health: Southworth, Harvey and Larson, *Use of Praziquantel for the control of Moniezia expansa in lambs* [1996] NZ Veterinary Journal 112. The inventive step was therefore to stand out against received scientific opinion and show prescience in realising that treating lambs for tapeworm is a sensible thing to do. On the other hand, the ordinary skilled man at the priority date would have thought that there was no point in providing such treatment and would therefore not even have started to look for a suitable agent.

11. Their Lordships have tried to do justice to this argument but they consider that it suffers from insuperable difficulties. In the first place, no trace of what is now alleged to have been the inventive step can be found in the specification. This states by way of background that helminthiasis is a widely occurring disease which has an adverse effect on farming economics. It goes on to refer to the narrow range of most anthelmintic agents, pointing out that one widely used preparation can treat roundworms but not tapeworms. It also mentions the growth of resistance to frequently used compounds and says that there is a need for a formulation which has the “breadth of activity” of the benzimidazoles (i.e. efficacy against round and tapeworms) but which is not affected by resistance. The prior art is therefore said to disclose a need for a preparation which is efficacious against both kinds of worm.

12. After the consistory clause, which is reproduced in claim 1, the specification mentions that for many years praziquantel has been used to control tape worms in humans and goes on to state:

“The surprising discovery that the efficacy of praziquantel can be enhanced in domesticated animals by simultaneous administration with other anthelmintics ... has been exploited in the present invention, which offers improved efficacy in the control of cestodes, together with simultaneous control of nematode infestations.”

13. The specification then goes on to describe various embodiments and the results of trials on lambs which showed that the preferred embodiments were efficacious in eradicating both kinds of worms. The first claim is for:

“1. 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 [a list of compounds used for treating round worms].”

14. The remaining claims are for compositions in accordance with claim 1 but subject to additional requirements and for methods of treating sheep in various ways with the claimed compositions.

15. Their Lordships consider that the specification teaches how to satisfy an existing need for a preparation which can treat both roundworms and tapeworms. It does not purport to identify a need

for the treatment of tapeworms which had previously been unrecognised.

16. The second difficulty is that, even if one could identify the inventive step as the idea of finding a compound to treat tapeworms as well as roundworms, it was not new. At the priority date, most New Zealand farmers were treating their lambs for tapeworm. Compounds for doing so were something “known or used before the priority date of the claim in New Zealand”. The fact that Dr Elliott may have thought it was perfectly useless does not mean that practising it, or having the idea of making a preparation to do it, was an inventive step. Otherwise anyone who adopted an obvious method for doing something which was widely practised but which the best scientific opinion thought was pointless could obtain a patent. As Gault J. said:

“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.”

17. This would indeed be a paradoxical state of affairs and their Lordships do not think that it is the law.