

BLO / 030 / 85

PATENTS ACT 1977

IN THE MATTER OF Application
No 8207610 in the name of
Ciba-Geigy AG

DECISION

The Examiner, Mr M J Price, having objected that the application includes claims to a method of treatment of the animal body by therapy contrary to Section 4(2) of the Act, the matter came before me at a hearing on 15 January 1985. Mr T Sharman appeared as agent for the applicants.

The invention is concerned with antihelminthic compositions and their use in controlling helminths in animals. Helminths are parasitic worms which may develop in the animal body, for example, in the intestinal tract of animals such as sheep, after the animal has picked them up, as eggs or in some other form, from the environment. An infestation of such worms in an animal is referred to as helminthiasis.

The invention resides in the discovery that a particular known antihelminthic compound represented in the specification by formula (1) when used together with a known type of antihelminthic compound represented by formula (11) shows a synergistic effect, and that the synergistic combination so formed is especially effective in combatting helminths which have developed a resistance to conventional individual antihelmintics, and especially those helminths known as nematodes.

According to the specification, the compounds are made up into compositions containing the compound of formula (1) and a compound of formula (11) together with suitable diluents, carriers or dispersants, and are generally administered to the animals orally as liquid or solid formulations in the form of solutions, emulsions, suspensions, powders, tablets, boluses or capsules, usually in the animals food, but they may also be administered by subcutaneous injection or by the pour-on method.

Claims 1 to 12 and 23 of the application refer to compositions for controlling helminths containing the combination of compounds of formula (1) and (11), and claims 13 to 17 refer to processes for making such compositions.

The synergistic effect of the combination of compounds was not known in the art and no objection has been raised to these claims which appear to be novel, inventive and capable of industrial application.

The examiner raised objection however to claims 18 to 22 which claim methods of controlling parasitic helminths, resistant helminths, nematodes and resistant nematodes by the use of the compositions, on the ground that such methods were treatments of the animal body by therapy and were therefore not capable of industrial application according to Section 4(2) of the Act.

Claim 18 reads:-

"A method of controlling parasitic helminths, which comprises the use of an active ingredient combination according to any one of claims 1 to 8."

The remaining claims 19 to 22 are similarly worded and refer to the controlling of resistant helminths, nematodes, resistant nematodes and resistant nematodes of two specified species.

In correspondence and at the hearing, Mr Sharman argued that the administration of the compositions to the animals does not affect the animal's body or its metabolism in any way, the action of the antihelmintic compounds being directed solely against the helminths. He also said that no prophylactic effect such as immunisation or vaccination occurs and the antihelmintic agents affect only the helminths without conferring any immunity on the animals. The analogy, Mr Sharman said, is with the treatment of lice which was allowed on appeal in Stafford-Miller's Applications 1984 FSR 258 rather than with the immunisation of poultry against coccidiosis which was refused on appeal in Unilever Limited (Davis's) Application 1983 RPC 219.

At the hearing Mr Sharman submitted a declaration by Dr Crowfoot of the applicant company to support his contention that no immunisation effect is produced and that the host animal's metabolism was not affected. Dr Crowfoot states that it is an intention to administer the compositions to healthy animals to prevent the reproduction of the helminths and kill them should they infest the animal, but without affecting the animals body. Such a treatment he refers to as "causal prophylaxis".

In order to highlight the distinction which he was seeking to make between "causal prophylaxis" and "therapy", Mr Sharman submitted an alternative set of claims 18 to 22 which claim methods of controlling helminths and nematodes by

applying the compositions to the helminths or nematodes or to their habitat.

Thus the alternative claim 18 reads:-

"A method of controlling parasitic helminths, which comprises applying to said helminths or to their habitat an antihelmintically effective amount of an active ingredient combination according to any one of claims 1 to 8".
The remaining claims 19 to 22 appear to suffer from omissions of wording but are evidently directed to similarly controlling nematodes including those of particular species.

I have considered Mr Sharman's arguments and Dr Crowfoot's evidence and I have no reason to doubt their view on the mode of action of the antihelmintic compositions of the invention. However I cannot accept that such a mode of action distinguishes the administration of these compositions from a method of therapy.

The meaning of the term "therapy" was considered during the appeal on Unilever (Davis's) Application 1983 RPC 219. In that case, Falconer J at page 228 lines 1 to 5 indicated that therapy in the context of Section 4(2) is correctly construed as a non-surgical method of medical treatment. He also concluded at page 230, last paragraph, that therapy includes "preventative, that is to say, prophylactic, treatment as well as curative treatment of disease of the human body and the animal body". At the very least, therefore, if it can be said that helminthiasis can be properly regarded as a disease then claims 18 to 22 must be directed to methods of therapy. In this context I note that the term "helminthiasis" is defined in the Shorter Oxford English Dictionary (3rd Edition) as "a diseased condition characterised by the presence of worms in the body", and that the Merck Manual of Diagnosis and Therapy (14th Edition, 1982) has a section at pages 247 to 260 entitled "Diseases caused by worms" and subtitled "Intestinal Nematodes". It therefore appears that there is some support for the opinion that helminthiasis is a disease.

When one comes to the wider view of therapy as non-surgical medical treatment then I think there can be little doubt that the treatment of helminths constitutes therapy. The applicants make clear in their specification that an infestation of helminth worms can result in restricted growth, damage to the animals and even death if not properly treated, and such a condition must be a proper one for medical treatment. When it comes to considering the corresponding treatment of, for example, tapeworm in human beings, I am sure that any doctor would regard this as therapy.

Turning to the continued administration of the compositions to healthy animals in order to prevent the development of an infestation, I would regard such treatment as prophylaxis. I do not think prophylaxis is limited to immunisation or vaccination but applies to any method of treating the human or animal body to prevent a disease, or any other undesired medical condition, from developing. Thus I think that causal prophylaxis as described by Mr Sharman and Dr Crowfoot is also a form of therapy.

With regard to Mr Sharman's reference to the decision on the treatment of lice in Stafford-Millers Applications 1984 FSR 258, I would say that this decision was taken under the 1949 Act where the criterion was whether the method could be said to comprise a manner of manufacture. At this time much consideration was given in such cases as to whether the method was one for treating the human body to cure or prevent disease (based on the Schering decision), and the Stafford-Miller case turned on whether an ectoparasite living on the outside of the body could be regarded as some sort of disease. However in his decision on this case, Whitford J said at page 261, last paragraph, "It may well be strange if a treatment of something inside falls within the prohibition and the treatment of something on the surface would not", as if the decision might have been different had endoparasites been involved as in the present case. In the same paragraph, Whitford J also considered that the treatment of ectoparasites such as lice lay on the absolute frontier in so far as the law was then concerned and the appeal was allowed on the "benefit of the doubt" principle. However the law has now changed and the criteria are now different, and I do not think that Stafford-Miller is an appropriate precedent to follow.

Finally, coming to Mr Sharman's alternative claims 18 to 22 which refer to the compositions being applied to the helminths or their habitat, I do not think that the change in wording from the original claims makes very much difference. The specification describes only the application of the compositions to the helminths when the latter are residing in the animal body, and the only habitat described in the specification is the animals body. Since such an administration must be effected by applying the compositions to the animal body, we are back to therapy again. As to applying the compositions to the helminths in any other environment or to any other habitat, there is no support in the description for any methods of this kind.

In the event therefore I support the examiner and I find that claims 18 to 22, whether in their original form or in the alternative form submitted during the

hearing, are not allowable in view of Section 4(2).

I therefore refuse to allow the application to proceed to grant with claims 18 to 22.

Dated this 25th day of February 1985

H R BAILEY

Principal Examiner, acting for the Comptroller

PATENT OFFICE