COMMISSIONER'S DECISION

1) LACK OF NOVELTY: Animal Feed
2) UNSTATUTORY, UNSUPPORTED:

The invention resides in the discovery that a specific concentration of a known antibiotic is effective against coccidiosis in animals. Claim 11 is rejected as not patentable over the composition claims since it does not specify the amount of antibiotic. Claims 12 to 17 related to the curative and preventative treatment of a disease as well as lacking proper disclosure support.

FINAL ACTION: Affirmed.

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated November 13, 1973, on application 030,226 (Class 167-180). The application was filed on September 18, 1968, in the name of Julius Berger and is entitled "Animal Feed". The Patent Appeal Board conducted a Hearing on July 16, 1975, at which Mr. R. Gould represented the applicant.

This application relates to an anti-parasitic composition which is effective in the treatment and control of coccidiosis. Coccidiosis is a disease caused by a protozon parasite and is a major problem in the poultry industry.

In the prosecution terminated by the Final Action the examiner refused claims 11 to 17. Pre-mix claim 11 is rejected as not patentable over the composition claims and claims 12 to 17 are refused as being directed to a judicially declared unpatentable process.

The examiner in the Final Action stated (in part):

The rejection of claim 11 is maintained and the reasons for such rejection is that, applicant discloses definite amounts of the active ingredient is useful in the treatment of coccidiosis and he supports this statement with toxicity tests and results showing the cure obtained. A concentrate or a premix to be diluted to the right proportions so as to provide the proper levels for effective cure or prevention of coccidiosis is a convenient packing form only, and therefore is not patentable over the composition claims.

The rejection of claims 12 to 17 is maintained and the reason for such rejection is that claims 12 to 17 are relating to a method of medical treatment which is not within the field of inventions as defined in Section 2 of the Patent Act and therefore a non patentable process.

In the recent decision of the Supreme Court handed down in December 1972 of "Tennessee Eastman Co. v. The Commissioner of Patents" Mr. Justice Pigeon gave his reasons for holding methods of treatment unpatentable, when he said:

> "In my view this necessarily implies that with respect to such substances, the therapeutic use cannot be claimed by a process claim apart from the substance itself. Otherwise, it would mean that while the substance could not be claimed except when prepared by the patented process, its use however prepared could be claimed as a method of treatment".

Further, his conclusion that methods of medical treatment are not processes within the meaning of "invention" in Section 2 of the Patent Act, can be seen in his following words:

> "Having come to the conclusion that methods of medical treatment are not contemplated in the definition of "invention" as a kind of "process ....."

Claims 12 to 17 are refused as being directed to a judicially declared unpatentable process.

The applicant in his response to the Final Action dated February 13, 1974 and February 10, 1975 stated (in part):

Claim 11 is directed to a pre-mix which can be used for preparing coccidiostatic compositions as defined in claim 1, this pre-mix comprising an active ingredient in association with an inert orally ingestible carrier. It seems to applicants that it is very clear that this claim is very different in scope from claim 1. Furthermore, its purpose and intent are different. Whereas claim 1 is directed to the coccidiostatic composition that would be suitable for feeding directly to animals affected by coccidiosis, claim 11 is drawn to a concentrate for producing such a coccidiostatic composition. As discussed on page 10 of the disclosure, when using the compounds of the invention, that is the antibiotic X-537 A or a pharmaceutically acceptable salt thereof, for treating or preventing coccidiosis, the coccidiostat (that is, the active ingredient) can be first compounded or blended with a feed ingredient or carrier to become a feed additive pre-mix, a feed concentrate, or a feed additive supplement. A feed additive, concentrate or pre-mix is an article intended to be diluted to produce a complete feed, i.e. an article intended to be administered as sole ration. Feed additive supplements, concentrates and pre-mixes contain a relatively large percentage of coccidiostats, i.e. the active ingredient, and are conveniently prepared by adding the active ingredient to a suitable carrier and mixing in a manner to give substantially uniform dispersion of the coccidiostat in the carrier.

In the normal course of events, the producer of the antibiotic which is the active ingredient of the compositions of his invention, would at most dilute the active ingredient with an inert orally ingestible carrier in order to produce such a pre-mix. It would then be left to other dealers, in particular, animal feed suppliers, to further dilute the pre-mix to produce a final coccidiostatic composition which would be sold to farmers for administration to animals. Relatively few manufacturers could be expected to produce the antibiotic and the pre-mixes. On the other hand, the dilution of the pre-mix in order to produce the final coccidiostatic composition suitable for feeding to the animals could be carried out by any number of feed suppliers, or even by the farmers themselves. Thus, it can be seen that claim 11 is a claim likely to be infringed only by the relatively few people who would be manufacturers and distributors of the active ingredient in the form of a pre-mix. In general, it is undesirable to sue the ultimate user of a composition for patent infringement, particularly where such an ultimate user might be the farmer. Accordingly, it can be seen that claim 11 is very necessary for the adequate protection of applicants' invention. It is a claim directed to one form of the composition aspect of applicants' invention, and it is not seen that it is proper to reject this claim as not patentable over the composition claims. A rejection of

> lack of patentability presupposes some piece of prior art which anticipates or renders obvious the claim rejected. It is clearly not the case in the Examiner's rejection of the claim 11. In the absence of a citation of relevant prior art, applicants believe they are entitled to the claim to the pre-mix as defined in claim 11.
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> Former claims 12-17 have been replaced by three new claims directed to the method of improving the efficiency of conversion of feed to weight gains in poultry. These three new claims are thus no longer directed to a method of medical treatment, but are rather directed to a method which it is believed the Office considers to be inherently patentable under the provisions of Section 2. Support for these revised method claims exists in the disclosure, ...

This application is based on the discovery that a specified concentration of the known antibiotic X537A and its pharmaceutically acceptable salts are effective against coccidiosis in animals. The effective amount is from .001% to .0125% of the active ingredient by weight of daily feed consumption.

Preparation of the antibiotic X537A is disclosed in the Journal of the American Chemical Society, Vol. 73, pages 5295-5298 (1951). On page 5295 the journal states that the antibiotic "is active in vitro against certain gram-positive bacteria and mycrobacteria," and that "tolerated dose levels showed no significant activity in vivo against a variety of bacterial and protozoan infections."

The applicant has, however, discovered that a composition of X537A comprising .001 to .0125 parts by weight of daily feed does combat coccidiosis. As Lord Simons stated in Raleigh Cycle Co. Ltd. v. H. Miller & Co. Ltd., (1948) 65 APC 141 at 148: "The discovery was the inventive step which gave to the invention the necessary merit."

In situations of this kind the Board is satisfied that the applicant may obtain novel composition claims which represent the inventive step in the discovery. The applicant may also be entitled to method of use claims provided such claims do not relate to medical treatment in the strict sense (curing or preventing disease).

In response to the Final Action the applicant has submitted amended claims 11 to 14 which replace refused claims 11 to 17. Amended claim 11 reads:

> A pre-mix useful for preparing by dilution a coccidiostatic composition comprising a compound selected from the group consisting of antibiotic X537A and pharmaceutically acceptable salts thereof in association with an inert orally ingestible carrier which is a solid carrier or a liquid carrier containing a surface active agent.

At the Hearing the applicant argued that a claim to the pre-mix should be allowed because that is the form in which a manufacturer of an antibiotic would merchandise it. He emphasized that it is a claim to one form of the composition aspect of the invention.

As previously mentioned the Board is satisfied that the applicant may obtain novel composition claims which will represent the inventive step in the discovery as set forth by the applicant. The discovery that a specified amount of the known antibiotic X537A, effective in combating coccidiosis in animals, is the inventive step which gives to the invention the necessary merit (Vide: Raleigh Cycle v Miller, supra), for it was originally thought that the antibiotic was not suitable for this purpose.

It is clear from amended claim 11 that no specific amount of the antibiotic is mentioned. This claim then does not represent a novel and practical application of the new discovery. The merit of the invention is completely lacking from the claim.

In supporting his position the applicant relied on Commissioner of Patents v Farbwerke Hoechst 1964 S.C.R. 49 at 53 wherein the court stated:

> A person is entitled to a patent for a new, useful and inventive medicinal substance but to dilute that new substance once its medical uses are established does not result in further invention. The diluted and undiluted substance are but two aspects of exactly the same invention. In this case, the addition of an inert carrier, which is a common expedient to increase bulk, and so facilitate measurement and administration, is nothing more than dilution and does not result in a further invention over and above that of the medicinal itself. If a patent subsists for the new medicinal substance, a separate patent cannot subsist for that substance merely diluted.

It is observed that the court refers to a new substance and not to a known substance. Furthermore, that situation related to a patent and to a pending application.

We are satisfied that claim 11 does not represent a novel and practical application of the new discovery and should be refused. It is observed that claims 1 to 10 satisfied this requirement and have not been refused.

Former claims 12 to 17 which relate to a method of curing and preventing disease have been replaced by amended claims 12 to 14. Amended claim 12 reads:

> The method of improving the efficiency of conversion of feed to weight gains in poultry due to coccidiosis which comprises orally administering to said poultry an effective amount of a compound selected from the group consisting of antibiotic X537A and pharmaceutically acceptable salts thereof, in admixture with a physiologically acceptable carrier for oral administration.

At the Hearing the applicant stated that disclosure support for these claims was found on pages 4, 9 and the table on page 21. Claim 12 specifies "the method of improving the efficiency of conversion of feed to weight gains in poultry." This of course would include treating uninfected chickens as well as treating infected chickens.

The statement of invention is given on page 4 of the application and reads:

> The present invention, therefore, is directed to a method of treating coccidiosis in animals, advantageously poultry, especially turkeys and chickens, by introducing into the gastro-intestinal tract of the animal infected with a causative pathogenic agent of the disease, a therapeutic amount of an antibiotic designated in the laboratory as X537A or its pharmaceutically acceptable salts, e.g., sodium, potassium, barium, and the like. The antibiotic is preferably employed in the crystalline form. Furthermore, the present invention is directed to a method for avoiding the development of coccidiosis in animals, especially poultry, which involves introducing compositions containing antibiotic X537A, preferably crystalline antibiotic X537A, or its pharmaceutically acceptable salts into the gastrointestinal tract of the animal prior to infection. Finally, this invention relates to coccidiostat compositions containing said antibiotic X537A.

There is little doubt but that the applicant regards his invention as relating or as being directed to methods and compositions relating to the treatment (curing or preventing) of coccidiosis.

A review of the disclosure reveals very minor references to improving the efficiency of conversion of feed to weight gains. In his response

of February 10, 1975 the applicant states "the table on page 21 wherein the chickens treated with the antibiotic exhibited gains of 105-108% compared with 100% for the untreated uninfected control chickens." While it is true that the table on page 21 shows a weight gain of 105-108% for infected chickens compared with 100% for untreated uninfected control chickens, it is observed that the table on page 19 discloses a weight gain of only 85%-92% for infected chickens compared to 100% for untreated uninfected chickens. In both the test results identical dosage of antibiotic was used. There is no question that a chicken which has been successfully treated for coccidiosis will regain its health and improve its weight as compared to an infected chicken. This inherent characteristic is to be expected in nature.

We are satisfied, therefore, that amended claim 12 lacks proper support in the disclosure, and is merely a new label for the previously refused claims 12 to 17, which claims related to curative or preventative treatment of a disease.

Claims 13 and 14, which are directly or indirectly dependent on claim 12, specify the carrier and active ingredient used. These are not of patentable significance and the remarks used to refuse claim 12 are applicable to them.

The Board is therefore satisfied that claims 11 to 14 should be refused for the reasons discussed.

J.F. HUGHES
Assistant Chairman,
Patent Appeal Board

I concur with the findings of the Patent Appeal Board and refuse to grant a patent on claims 11 to 14. The applicant has six months within which to delete these claims, or to appeal this decision under the provisions of Section 44 of the Patent Act.

Decision accordingly,

A.M. Laidlaw,
Commissioner of Patents

Dated at Hull, Quebec
this 27th day of August, 1975

Agent for Applicant

Fetherstonhaugh & Co.,
Box 2999, Station D,
Ottawa, Ontario.
K1P 5Y6