COMMISSIONER'S DECISION

Sections 41 & 2 - Treating Hens for Moulting

A method of injecting hens with a hormone to shorten the period of moulting of feathers so that they resume egg-laying more quickly was held to be unpatentable subject matter.

Rejection affirmed.

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A Hearing before the Patent Appeal Board took place on February 15, 1978 to consider the final rejection by the examiner of patent application 182923, Class 167/113. The application had been filed on October 9, 1973. by Eisai Ltd., a Japanese company, as assignee of Etsuo Naito et al. The invention is for a Method for Facilitating Egg-Laying Recuperation of Hens during Moulting. The applicant was represented by Mr. Neville Hewitt.

The first five claims of the application, which were refused, are directed to administering LH-RH (a porcine hypothalmus extract) to molting hens by intramuscular injection. LH-RH can also be prepared by chemical methods. The acronym LN-RH stands for "Luteinizing Hormone-Releasing Hormone." An injection shortens the period of moulting so that the hens resume egg laying more quickly. This increases the annual rate of egg-laying, and consequently is important economically. The sixth claim is for a composition containing LH-RH used in the method, and has not been rejected Claim 1 is representative of the rejected claims:

> A method for improving egg-laying recovery of a normally healthy hen during moulting which comprises administering LH-RH through intra-muscular injection to the moulting hen.

The Examiner refused the method claims on the ground that they are not directed to patentable subject matter, and relied on Section 2 of the Patent Act as the basis for his rejection. He has said the method is a medical treatment, and that medical treatments are not patentable. In support of

that contention he pointed to the remarks of Mr. Justice Pigeon in Tennessee Eastman v. Commissioner of Patents 1947 S.C.R. 111, where it was said that methods of medical treatment are not contemplated in the definition of invention, and that a therapeutic use cannot be claimed by a process claim apart from the substance itself.

The examiner also referred to the fact that the substance injected secretes hormones capable of forming corpus luteum, which affect bodily functions of the chicken. In his view it is a medicinal substance useful in therapy and as a contraceptive. In addition he directed attention to the definition of a drug in the Food and Drug Act (1970) R.S.C.F.-27, Section (2) as "any substance for use in modifying organic functions in man or animal." For such reasons he held LH-RH to be a drug, and its administration as a medical treatment. He says that the application of a substance, even to a healthy body, to modify an organic function is a medical treatment.

Mr. Hewitt, for his part, has contended vigorously that the process in question is not a medical treatment. He says the hens treated are not ill, that the treatment does not prevent them from becoming ill, and that what is done is a commercial process for increasing egg production. He asserts that a moulting hen is not ill, and moulting is a normal part of a hens natural annual life cycle. The treatment is essentially a process for reducing the moulting period during which the hen does not lay eggs.

The applicant has also drawn attention to the Commissioners prior decision on Patent 882618, Thrasher, Oct. 5, 1971, where claims to feeding swine were accepted. That decision was taken, however, before the Tennessee-Eastman v Commissioner of Patents case was concluded. We must consequently turn to more recent decisions of the Commissioner, such as that respecting application 047754 of IMC Chemicals (Patent Office Record, December 20, 1977, p.xiv) and that published in the P.O.R. of May 23, 1978, p. xiv (in which the decision given earlier on patent 882618 was considered), and where claims to feeding animals were refused.

At the Hearing (and in his written submission to the Board at that time), Mr. Hewitt did in fact discuss in considerable detail the 047754 decision. We must consequently give attention to it. The invention involved increases the growth rate of animals by feeding them certain chemical substances. In rejecting the claims it was said

> We are persuaded, however, that the substance modifies the organic function of the body. The substance claimed is a hormonal compound which exhibits extrogenic activity. We are satisfied that it is "a biological agent," and, in our view, it is a "medicine" within "the broad meaning" (See the ICI Decision supra). Any substance taken orally which affects the metabolism of the body must, of necessity, be classed as a "food or medicine." Furthermore there is no doubt that the substance is produced by a chemical process. In addition, in Dextran Products v.Benger Laboratories (1970) 60 C.P.R. 215 the Commissioner of Patents rejected completely a submission that a veterinary product used to promote weight increase in piglets is not a medicine within the meaning of Section 41 of the Patent Act.

In reaching that conclusion, consideration was given to the decisions of Tennessee Eastman v Commissioner of Patents 8 C.P.R.(2d) 202; Parke, Davis v. Fine Chemicals (1959) S.C.R. 219 at 226 and (1957) Ex. C.R. 300 at 307; and Imperial Chemical v. Commissioner of Patents (1967), Ex. C.R. 57 at 60. Those decisions have given a broad interpretation to the meaning of a medicine as used in the Canadian Patent Act. In an appendix to the ICI decision, Mr. Justice Gibson said, inter alia:

> 2. "Medicines" are today categorized under specifics such as antihistimines, anti-infectives, autonomic drugs, cardio vascular drugs, antianemia agents, hemostatics, diagnostic agents, expectorants and cough preparations, gastrointestimal drugs, hormones, local anaesthetics, oxytocics, vitamins, and spasmolytic agents and so forth.... [We have underlined "hormones" because what we are concerned with here is a hormone.]

Reference was also made in the 047754 decision to the definition of "drug" in the Food and Drug Act, 1970 R.S.C. F-27, Sec. 2 as "any substance for use in modifying organic functions in man or animal.

Mr. Hewitt attacked the 047754 decision because of the statement in it that "Any substance taken orally which affects the metabolism of the body must, of necessity, be classed as a "food or medicine." He points out that poisons are substances affecting the metabolism of the body, but they are not considered to be medicine. We believe, however, that the statements made in the 047754 decision must be taken within the context in which they were used, and not in isolation. Most if not all substances are poisonous if used in sufficient quantities or under certain conditions. Even the most benign medicines can be used as suicidal or homicidal agents if administered in excess. That does not mean, however, that when properly used and controlled they are not medicines in the normal sense of the word. Otherwise we must say there are no medicines at all because everything can be poisonous. Even the LH-RH hormones of the present invention is doubtlessly harmful and poisonous if improperly used. But properly used it does quickly bring the hens back to their desired egg-laying condition, which is their usual and therefore normal state.

We note that LH-RH is "administered" (to use the wording of the claim, with its connotation of giving or applying medicine) by intra-muscular injection, in itself a veterinary, or at least a para-veterinary procedure.

We are, consequently, satisfied that we are considering one type of medicinal treatment used to alleviate and reduce an undesired condition in hens, and that such a treatment is unpatentable under the Canadian Patent Act.

We also question whether animal husbandry, poultry care and similar farming procedures are proper subject matter for patent protection. In the Matter of Application for Patent by Rau G.m.b.H. (1935) 52 RPC 362 it was held that selective breeding of animals and cultivation of plants to improve stocks is not patentable subject matter. In both R.H.E.'s Application (1944) 61 R.P.C. and Lenards Application (1954) 71 R.P.C. 190 fruits and other growing crops were excluded from patent protection. In the matter of N.V. Philips Gloeilampen-fabriken (1954) 71 RPC 1952, a process for raising poinsettia plants by controlled exposure to light was refused because the court could not "escape

from the conclusion that the invention still resides in the modification of climatic conditions, the production of the end product being the inevitable result of that which is inherent in the plant." In the Matter of A.D. Goldhaft et al, 1957 RPC 276, it was decided that sex controlled eggs must, like fruit and growing crops, be excluded from patent protection. In the Matter of American Chemical Paint (1958) RPC 47 a process for defoilating cotton plants prior to harvesting was refused.

In the Canterbury Agricultural College Case, 1958 RPC 85, process claims for improving the wool yield of sheep by administering to them a veterinary composition were also rejected.

For such reasons we are satisfied that claims 1-5 inclusive were properly refused.

Gordon Asher
Chairman
Patent Appeal Board, Canada

Having considered the arguments made by the applicant and examiner, and the recommendations of the Patent Appeal Board, I now refuse claims 1, 2, 3, 4 and 5. They must be removed from this application within six months if no appeal is taken, under Section 44.

J.J.A. Gariepy
Commissioner of Patents

Dated at Hull, Quebec
this 8th. day of June, 1978

Agent for Applicant

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