COMMISSIONER'S DECISION

SECTION 2 - Method of Improving the rate growth of animals.

It was held that a product used to promote weight increase in animals is a "medicine" within the meaning of Section 41 of the Patent Act.

Rejection: The refusal of the claims to the method of use of the product was affirmed.

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated May 2, 1975, on application 047,754 (Class 260-302.5). The application was filed on April 3, 1969, in the name of Wehrmeister, Herbert L. et al, and is entitled "Linked Fused Carbocyclic 5 Membered Heterocyclic Compounds." The Patent Appeal Board conducted a Hearing on June 2, 1976, at which Messrs. D. Watson, Q.C. and Mr. F. Pole represented the applicant.

The application relates to heterocyclic compounds which exhibit estrogenic activity or aid in increasing the rate of growth in meat producing animals.

In the Final Action the examiner refused claims 46 to 66 as not falling under Section 2 of the Patent Act. He cited as authority the decision on Tennessee-Eastman v The Commissioner of Patents (CPR 8 2nd. series, 202).

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

> Claims 46 to 66, which are directed to a method of increasing the body weight of normally healthy meat-producing animals, are again rejected in view of the Tennessee-Eastman vs. the Commissioner of Patents C.P.R. 8, 2nd. series, 202. As mentioned in the Office Actions of October 9, 1973 and January 31, 1974, since this application is governed by Section 41(1)

of the Patent Act, the scope of the compounds of the invention is restricted as they must be dependent upon their process of preparation. Therefore the method of use of the compounds of the invention cannot be claimed by a process claim apart from the substance itself. Otherwise it could mean that, while the compounds could not be claimed except when prepared by the patented process, their use however prepared could be claimed as a method of treatment. Therefore these "method of use" process claims are giving the applicant an easy way out of the restriction of Section 41(1) of the Patent Act.

The applicant's position is shown from the following paragraphs in his request for review:

...

We submit that the Examiner's assumption that Section 41(1) applies is inconsistent with recent decisions of the Supreme Court of Canada as well as being inconsistent with a previous ruling of the Commissioner of Patents.

In the recent decision of Burton-Parsons Chemicals Inc. vs. Hewlett Packard Canada Ltd. Pigeon J., who delivered the decision of all nine members of the Supreme Court of Canada, stated as follows:

> "... I agree with the trial judge's finding that this cream is not 'intended for medicine' within the meaning of S. 41. Cases on the meaning of this expression were recently reviewed in Tennessee Eastman vs Commissioner of Patents (1974 S.C.R. 111). Substances intended for use in surgery were held to be included. I have no doubt that a conductive cream is apt to be used whenever electrodes are applied to the skin during surgery. However, there is nothing in the evidence which would justify the conclusion that such is the main or primary use of the product. It is clear that such is primarily and mainly for the taking of electrocardiograms in routine examinations, not necessarily or mainly in connection with the treatment of diseases."

This quotation clearly establishes the following propositions:

(1) Not everything administered to the body is necessarily a medicine;

(2) "Medicine" requires the treatment of disease;

(3) The main or primary use is to be considered. Even more specific to the facts of this case is the Tennessee Eastman decision of the Supreme Court of Canada (1973) 8 C.P.R. (2d) 202 at page 208, where it was stated:

> "In the second place, what was actually decided in those cases is not related to a medical or surgical method. Swift's application dealt with a method of tenderizing meat by injecting enzymes into the animal before slaughtering".

...

It is well established that methods will be regarded as medical only if they involve the treatment of disease. We have already noted the Burton-Parsons case in support of this proposition. If any further authority is needed, it will be found in Schering AG's Application (1971) R.P.C. 337 at page 344, where applicant's argument was accepted "that a process for contraception is not a process for 'medical treatment' in the sense of treatment to cure or prevent disease and that the established practice relates only to medical treatment". The Schering case was referred to with approval in the Tennessee Eastman case at page 209 and emphasis was added in a quotation to the statement that "patents for medical treatment in the strict sense must be excluded". Yet another authority is Joos vs Commissioner of Patents (1973) R.P.C. 59, particularly at page 65, where it is stated:

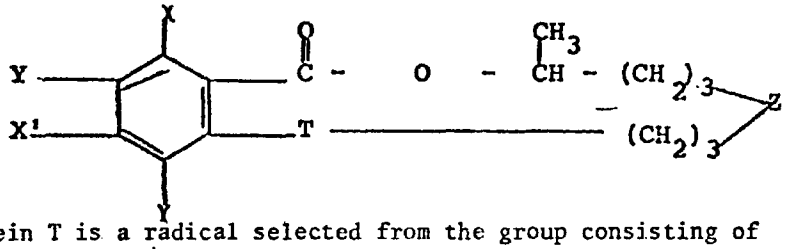
> "To be treatment, in the relevant sense, it seems to me that the purpose of the application to the body whether of a substance or a process must be the arrest or cure of disease or diseased condition or the correction of some malfunction or the amelioriation of some incapacity or disability"

The claims in question are directed to the treatment of "normally healthy" meat-producing animals. It is therefore evident that the substances are not being administered for the treatment of disease. In this connection, emphasis is placed on the principle established by the Burton-Parsons case that the main or primary use must be considered. It is of no importance that there might be the occasional diseased animal.

...

Either the method for which protection is sought falls within Section 41(1) as interpreted by decisions such as the Tennessee-Eastman case and the Burton-Parsons case, or it does not. It does not matter whether the compound used in the process is new or old. It is submitted that the Commissioner's decision in Application 862,758 was correct and is in accordance with the laws as established by Tennessee Eastman and Burton Parsons, that no proper basis for distinction exists on the facts, and that it should be followed.

The issue to be considered is whether claims 46 to 66 which are directed to a method of increasing the rate of growth of normally healthy meat-producing animals, using a new substance, are allowable. Other allowable claims in the application relate to novel compounds and the process of preparing them. Claim 46, which is illustrative of the refused claims, reads as follows:

> A method of increasing the rate of growth of normally healthy meat-producing animals which comprise feeding to said animals a feed composition which includes a growth-promoting amount of a compound having the formula
>
> 
>
> wherein T is a radical selected from the group consisting of -CH=CH- and $-CH_2CH_2-$; Z is a radical selected from the group consisting of $=C=O$, $=CH_2$, and =CHOR; R is selected from the group consisting of hydrogen, lower alkyl, lower acyclic acyl radicals, and monocyclic aralkyl radicals containing up to about 10 carbon atoms; X is selected from the group consisting of hydrogen, -OR and -OR'; R' is selected from the group consisting of benzoxazolyl, benzothiazolyl and phenyltetrazolyl; X' is selected from the group consisting of X and tetrahydropyranyloxy; Y is selected from the group consisting of hydrogen, amino, nitro and hydroxyl; and provided that unless at least one of X and X' is selected from the group consisting of tetrahydropyranyloxy, benzoxazolyloxy, benzothiazolyloxy, and phenyltetrazolyloxy, then at least one of X and X' is hydrogen.

At the hearing Mr. Watson ably discussed the jurisprudence relating to the matter before us. He also strongly urged, both in his written and oral submissions, that he is not claiming a medical treatment. It was conceded by Mr. Watson that medical treatments are unpatentable (cf. Tennessee Eastman v Commissioner of Patents 1970 Ex. C.R. as reported in (1970) 62 C.P.R. 117; 1974 S.C.R. 111). The thrust taken by the applicant's argument is that before a process can be considered medical it must be related to curing or preventing a disease. He contends that the treatment of normally healthy meat-producing animals, as claimed, "does not involve a medical treatment in the sense to cure or prevent disease."

The applicant directed our attention to the allowance in the United Kingdom of several applications relating to similar subject matter presently before us. It will suffice, we believe, to say that prior to 1962 in the U.K. any treatment of humans or of animals was not considered to be patentable subject matter. With the findings in N.R.D.C.'s Application (1961) 1 R.P.C. 134 (an Australian decision), Swift's Application (1961) R.P.C. 141 (a New Zealand decision) and Swift and Company's Application (1962) R.P.C. 37 (a British decision) however, there has been a change. Distinctions have been made between processes applied to animals and those applied to humans, and the scope of what has been considered a medical process has been narrowed. At that time (1962), however, there was no appeal beyond the Patent Appeal Tribunal. This was a significant factor in the allowance of the Swift case (and others that followed), for if it did not proceed no further judicial review was possible.

The Canadian Courts have given a broad interpretation to the meaning of medicines. See, for example, p. 119 of the Tennessee Eastman decision supra (S.C.); Parke, Davis v Fine Chemicals (1959) S.C.R. 219 at 226, confirming (1957) Ex. C.R. 300 at 307; and Imperial Chemical v. Commissioner of Patents (1967) 1 Ex C.R. 57 at 60. In the latter we also find at page 61: " 'I agree with Thurlow, J. that the word 'medicine' as used in s. 41 of the Act, should be interpreted broadly ....' "

As an appendix to the I.C.I. decision, Mr. Justice Gibson provided a series of definitions for both medicines and drugs. He goes on to say: (emphasis added)

> A perusal of dictionary definitions, judicial decisions and text book authorities leads to the conclusion that there is both a restricted definition and a broad definition of "medicine" commonly and generally understood and used. The method by which this conclusion is reached may be stated briefly:
>
> 1. A "medicine" in modern parlance has come to mean, inter alia, a drug, a therapeutic agent, a biological agent, and a pharmaceutical specialty.

2. "Medicines" are to-day categorized under specifics such as antihistamines, anti-infectives, autonomic drugs, cardiovascular drugs, antianemia agents, hemostatics, diagnostic agents, expectorant and cough preparations, gastrointestinal drugs, hormones, local anaesthetics, oxytocics, vitamins, anaesthetics, and spasmolytic agents and so forth. In other words, generally speaking, it is seldom that anyone speaks of "medicines" anymore....

3. All of these specifics may be referred to merely as medical drugs or medical agents, without further categorizing as in 1 above.

4. Some of these medical drugs or medical agents are used to cure or heal a patient per se, and are sometimes referred to as therapeutic agents (even though there are many therapeutic agents which do not cure or heal per se, but are used for a particular purpose in the treatment of a patient), while others are used in the course of the whole treatment of the patient. In this connection, for instance in the case of the former kind of medical drugs or medical agents, an antibiotic, say, e.g., penicillin, comes closest perhaps, but even then, it often happens that other medical drugs or agents are necessary as supportive therapy when the antibiotic appears to be specific for a particular type of infection.

5. The former kind of medical drugs or agents are "medicines" in a restricted meaning, while the latter kind are "medicines" in the broad meaning.

"Halothane" is not a medical drug or agent that cures per se, but instead is a medical drug or agent used in medicine in the treatment of patients and is an integral essential part of surgical therapy of disease, a part of the therapeutic regimen.

Therefore in my opinion, "Halothane" is a substance intended for "medicine" within the meaning of s. 41(1) of the Patent Act, and as consequence, the appeal is dismissed with costs.

To the above we would add the definition of "drug" already provided by Parliament (for the purpose of the Food & Drug Act, (1970) R.S.C. F-27, Sec. (2)) as "any substance for use in modifying organic functions in man or animal." (emphasis added)

The applicant states (in response to the Final Action) that the substances "have a physiological effect on the growth pattern [of the animal]...." Surely this would be considered as having modified the organic function

of the animal, and could appropriately be considered as "a biological agent" viz. "a medicine." He goes on to say that: "The situation is therefore undistinguishable from the Swift application which application the Supreme Court specifically found not to be related to a medical method." The Swift decision related to a situation where an enzyme was injected into an animal for the purpose of tenderizing meat. We must remember, however, that in the Swift decision the action of the animal's body was purely mechanical and non-metabolic. In any event Mr. Justice Pigeon in Tennessee Eastman v. Commissioner of Patents (1974 S.C.R. 111 at 120) made it clear that caution must be exercised in transposing from a United Kingdom context to Canadian law the conclusions of the Swift and N.R.D.C. decisions.

Mr. Watson drew our attention to a decision of the Supreme Court of Canada in Burton Parsons Chemicals v Hewlett-Packard, (1974) 4-17 C.P.R. (2d); and in particular to p. 18, where Mr. Justice Pigeon concluded that a case had not been made that a cream used for taking electrocardiograms in routine examinations is a medicine. Such compositions differ, however, from a substance taken into the body itself, and affecting an internal body process. On such a basis the subject matter before us is, in our view, closer to that considered in the Imperial Chemical v. Commissioner of Patents case supra than what was considered in Burton Parsons.

We think it is fair to say that the experts in the field are not sure just why a particular substance, when added to animal food, increases the rate of growth of the animal. The effect, however, of using an antibiotic in animal food may be of interest. It was discussed in the book entitled "Microbiology." (Published by McGraw-Hill Book Co. 1972 - author, Mr. M.J. Pelczar.) Page 487 reads as follows:

> Antibiotics are now widely used as growth stimulants in poultry and livestock feeds. After the discovery that many domestic food-producing animals require vitamin B_{12} for optimum growth when fed a diet consisting of plant protein, it developed that

> by adding wastes from fermentation by-products to feeds, growth was stimulated more than by B_{12} alone. Even when adequate amounts of B_{12} were present in the diet, more rapid growth of young animals was noted when they were fed mash from the antibiotic fermenters. Use of pure antibiotics has given similar results. Commercially, the addition of Aureomycin, Terramycin, or penicillin to swine or poultry feeds at the rate of 5 to 20 g per ton of feed increases the rate of growth of young animals by at least 10 percent and sometimes by as much as 50 percent. This use of these substances is so important that antibiotics for medical purposes may become the by-product of the crude residues in fermenters produced for use as food supplements.
>
> The stimulating effect of antibiotics on growth of domestic animals may be explained in several ways:
>
> 1 The antibiotics may destroy bacteria and other intestinal parasites that cause subclinical disease and retard growth and development. For example, it has been suggested that pigs respond dramatically to the addition of Terramycin to their diet because the antibiotic inhibits the growth of Clostridium perfringens in their intestines and prevents or reduces a chronic but subclinical toxemia.
>
> 2 Removal of the saprophytic bacteria from the intestinal tract may have a beneficial effect on the nutrition of the animals.

Further, T.H. JUKES in the Journal of the American Medical Association (April 21, 1975 Vol. 232 No. 3) reports that antibiotics will promote growth by inhibiting intestinal micro-organisms. Volume 232 starting at line 1, reads as follows:

> The use of antibiotics in feeding animals is connected in a remarkable way to clinical medicine, for this use came as a by-product of the discovery of a new antibiotic, aureomycin (now known as chlortetracycline), in 1948. Aureomycin was the first of the tetracyclines, and it was immediately put to use for its "broad-spectrum" effectiveness against many pathogenic microorganisms.

At line 22 he goes on to state:

> A few grams of antibiotics such as a tetracycline, penicillin, or streptomycin in a ton of feed will increase growth, apparently because farm animals normally harbor susceptible intestinal microorganisms that are mildly deleterious without being frankly pathogenic.

He also refers to "the extensive use of antibiotics in veterinary medicine for 25 years. The report by this committee [Swann] led to the principal antibiotics for farm animals being placed on veterinary prescription in Great Britain...."

The above information was brought to the applicant's attention before the hearing. At the hearing Mr. Watson made it clear that the substance of this application was not an antibiotic. There is, however, no explanation, as to what produces the increase in the rate of growth when using the substance of the instant application.

We are persuaded, however, that the substance modifies the organic functions 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" in "the broad meaning" (See the I.C.I. Decision supra.). Any substance taken orally which effects 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.

The applicant argues that he is not offending Section 41 of the Patent Act because he has claimed the product in process dependent form in other claims as required by that section.

In Tennessee Eastman v Commissioner, supra, however, Pigeon J., at page 118, stated:

> Section 41 was enacted for the purpose of restricting the scope of patents "relating to substances prepared or produced by chemical processes and intended for food or medicine". The first principle proclaimed is that in the case of such inventions, "the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described in the claim or by their obvious equivalents". 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. In other words, if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s. 41(1). (emphasis added)

The applicant referred to a previous decision (on application 862,758) of this Board relating to "methods of improving the rate growth of animals." That decision was made prior to the Tennessee Eastman v Commissioner of Patents (S.C.) decision supra. As a matter of fact it was the rationale of the Tennessee Eastman decision that predicated the Final Action refusing the present method of use claims.

The applicant's attention is directed to an article in the 1974 edition of the "Ottawa Law Review" Vol. 6 entitled: "Industrial Property," which is of interest. In referring to the above Patent Appeal Board decision on application 862,758 the writer states at page 475: "It is not clear whether this decision can stand in view of the Supreme Court decision in Tennessee Eastman, as this would appear to be a method of using a veterinary food, which would appear to fall under Section 41 of the Patent Act, if the Tennessee Eastman argument is followed."

There is one other point. When we consider the large number of compounds used in the process of claim 46, we find they run to tens if not hundreds of thousands. While obviously they all possess certain structural similarities, we are not convinced that so many compounds do in fact promote growth rates in animals, nor that it can be seriously contended that they do. Undoubtedly this comes close to the type of overclaiming found objectionable in Boehringer Sohn v Bell Craig, 1962 Ex. C.R. 201, and elsewhere. Since, however, there were other grounds for rejecting claim 46, this point need not be explored further.

In summary, we are satisfied that the present claims are directed to a method of treatment with a biological agent (hormonal compound), which modifies the organic functions of the body, and should not, in our view, be claimed as a

process apart from the drug itself. (Vide, Tennessee Eastman v Commissioner, supra.)

We recommend that the decision in the Final Action refusing claims 46 to 66 "as not falling under Section 2 of the Patent Act" be affirmed.

J.F. Hughes
Assistant Chairman
Patent Appeal Board

I concur with the findings of the Patent Appeal Board. Accordingly, I refuse to allow claims 46 to 66. The applicant has six months in which to cancel claims 46 to 66, or appeal this decision under the provision of Section 44 of the Patent Act.

J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec

this 13th day of August, 1976

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