COMMISSIONER'S DECISION

SECTION 2: Double Patenting - 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. The application was also rejected for double patenting since it is a divisional with claims directed to the intended use of the antibiotic which was patented in the parent application.

Rejection: Affirmed on both grounds.

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated December 4, 1975, on application 207,229 (Class 99-28). The application was filed on August 16, 1974, in the name of Norimasa Miyairi et al, and is entitled "Method Of Improving Rate Of Growth Of Animals."

This application is a divisional of application 098757 which issued to patent (960,168) on December 31, 1974. The application relates to a method for improving the rate of growth of non-human animals by the administration thereto of growth promoting amounts of the antibiotic "thiopeptin A_4" (the antibiotic was claimed in the above-mentioned patent). Claim 1 of this application reads as follows:

> A method of improving the rate of growth of a normally healthy non-human animal comprising feeding said animal a feed containing thiopeptin A_4 and a non-toxic carrier, in an amount effective to improve the rate of growth.

In the Final Action the examiner refused the claims of the application on the ground that "they claim unpatentable subject matter viz., the medical treatment of non-human animals," and also that the claims are directed to the intended use of the antibiotic which was allowed in the parent application (patent 960,168). In that action the examiner stated (in part):

Claims 1 to 3 claim unpatentable subject matter viz the medical treatment of non-human animals. It is submitted that the effect of the antibiotics on growth is due to the antibiotics effects on parasitic and/or saprophytic organisms present even in subclinical levels in the animals. By eliminating these organisms or by preventing these organisms from using nutrients, more nutrients become available to the animal and thus growth promotion is achieved. Due to the many variations in chemical, physical and structural properties of the antibiotics known to induce faster growth, it is certainly not totally unfounded to postulate, in the absence of evidence to the contrary, that the growth promotion effects of these substances is mainly due to their common antibiotic property i.e. that of eliminating parasites and/or saprophytes or preventing them from carrying out their normal functions. Because the visible and measurable effects of the antibiotics on the animal is one of growth promotion and not of curing a disease (because of subclinical levels of parasites and/or saprophytes) one cannot reasonably conclude that there is no medical treatment. In fact, the contrary conclusion is most evident based on the present knowledge of antibiotics.

Further, claims 1 to 3 define an obvious method of use of a compound found allowable to the inventor in one application. Such claims in a different application of the same inventor are not allowable.

The applicant's response (in part) is indicated by the following paragraphs:

...

It is pointed out that the claims of the present invention are directed to a method of improving the rate of growth of normally healthy non-human animals as opposed to animals which are in a sick or diseased condition. It is believed that it is well established that terms such as "medicine" must be interpreted in their ordinary sense as laymen would employ them (Imperial Chemical Industries v. Commissioner of Patents, 51 C.P.R. 102); and it is submitted that the same should apply to "a medical treatment" and only those methods should be considered "medical treatments" which would in the ordinary sense to a layman be considered as medical treatments.

...

Particularly it will be noted that the method of the present invention"does not apply any pharmaceutical properties of a substance to effect a curative or preventive treatment of an ailment"; and certainly "no step of medical or surgical treatment is set out in the claims".

Certainly it will be appreciated that the present method is not one which in use will restrict the professional skills of the surgeon or doctor. On the contrary, the method will be carried out by non-medical personnel and in particular by farmers and their employees.

> Reference is further made to the decision of the Patents Appeal Tribunal in the United Kingdom in the matter of Schering AG's application. This decision was referred to by the Board in the aforementioned Commissioner's decision* and was concerned with claims directed to a method of contraception without suppression of ovulation. The claims had been rejected as being directed to a method of treatment of human beings. The Patents Appeal Tribunal were apparently of the opinion that such a method was not necessarily a "medical treatment" at any rate in the narrower sense of treatment to cure or prevent a disease.
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> ...
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> Attention is further directed to Canadian patents 890,188 and 882,618, both of which are directed to methods of improving the rate of growth of animals; both of these patents were granted after appeal to the Commissioner and these are reported in The Patent Office Record of February 15, 1972 and October 5, 1971. The claims of the present invention are similarly directed to method of improving the rate of growth of animals which are not in a diseased condition but in a healthy state.

We note in the parent application, which issued to a patent, that the essence of the invention resides in the discovery of the useful properties of the antibiotic. That utility was stated as: "The theopeptin A_4 component also possesses antibacterial activities against a number of micro-organisms and is useful for an animal feed supplement. It is observed that the same utility is given in the present application and reads as follows: "The thiopeptin A_4 component possesses antibacterial activities against a number of microorganisms and is useful as an animal feed supplement."

The question which should be asked at this time is whether or not there is a second invention. The applicant is entitled, of course, to only one patent for one invention, and claims which differ in no material way should not be allowed in separate patents. Section 28(1) of the Act authorizes the granting of a patent, but not of several patents for an invention. Section 46 provides that a patent shall give an exclusive right in the invention, a condition antagonistic to the existence of other patents for the same inventive concept. Section 63(2) also reflects the same principle of patent law, one supported by Montecatini v Standard Oil (1974) 14 C.P.R. (2d) 190 at 194, where we find:

* Reported in the Patent Office Record of April 16, 1974.

> ...the case of Commissioner of Patents v Farbwerke Hoechst Aktiengesellshaft Vormals Meister Lucius & Bruning (1963) (1964) S.C.R. 49 and In the Matter of Two Applications for Patents for Henry Dreyfus (1927) 44 R.P.C. 291, are authority for the proposition that there can be only one patent for any given invention.

See as well Amoco v. Texaco Exploration, Fed. Ct. C., August 13, 1975.

This is not to say, however, that in a proper case a second patent might not issue where the essence of such an invention was the discovery of a new and unobvious utility different than that found in the first patent.

The claims in our view, though independent of one another, cannot be read apart from the description of the invention in the specification. The applicant has in no way shown that the present claims are directed to a separate invention distinct from the product (antibiotic) claims. It is clear that the present claims are directed to the intended use of the antibiotic which was allowed in the parent application in 1974. The present utility is the same as that upon which the patentability of the antibiotic was predicated.

We are therefore satisfied that there is no further invention in the present application in having claims "directed to the intended use of the antibiotic," beyond that protected in the patent which claims the antibiotic. That is, the present claims are merely directed to a different aspect of the same invention as that of the parent. To permit a new grant now would create an unlawful extension of monopoly for the invention.

The Board is mindful of course that there is no direct jurisprudence on the matter of double patenting, but we will refer to the recognition of it in Lovell Mfg. Co. v Beatty Bros, Ex. C.R. (1958) 23 Fox Pat. C. 112 at 159, where it is stated: "There is no Canadian decision on the subject of double patenting...." But in referring to the attack of "double patenting," the court went on to consider it by saying:

> Finally, the basic objection to double patenting is that it would extend the life of the monopoly if a patent were granted for a device and a patent for the same device were granted subsequently. This did not happen in the present case for two patents referred to, indeed, the plaintiffs three patents were issued on the same day. This puts an end to the matter.

If we are correct in our view that there is no second invention, then there is no need to decide whether the claims are directed to a method of "medical treatment." We will, however, consider this point as well. We are of course mindful that methods of medical treatment are unpatentable (Vide, Tennessee Eastman v Commissioner of Patents (1970) Ex. C.R. as reported in (1970) 62 C.P.R. 117; 1974 S.C.R. 111).

We note that the thrust taken by the applicants' argument is that before a method can be considered as directed to "medical treatment" it must be related to curing or preventing a disease. The word "medicine" however, in our view, should be given a broad interpretation. A typical dictionary description of the word is that it is "the science and art concerned with the cure, alleviation and prevention of disease, and with the restoration and preservation of health" (Oxford Dictionary).

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 therea-peutic 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)

It appears from the above that Mr. Justice Gibson considered an antibiotic "in the broad meaning" to be a medicine.

The applicant 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.

In a previous response the applicant submitted a page from a book entitled "Microbiology," (Published by McGraw-Hill Book Co. 1972 - Author: Mr. J. Pelczar) where growth stimulation by antibiotics is classified under the heading of nonmedical uses of antibiotics. On the same page, however, the bacteria destroying effect of antibiotics is discussed. That portion 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 to this postulate 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 microorganisms. Volume No. 3, 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 <u>veterinary medicine</u> for 25 years. The report by this committee (Swann) led to the principal antibiotics for farm animals being placed on <u>veterinary prescription</u> in Great Britain...." (emphasis added)

These demonstrate that we are considering a form of "medical treatment" to cure chronic although subclinical bacterial infections, in farm animals. In addition, in <u>Dextran Products v Benger Laboratories</u> (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.

It is interesting to note the definition of a medicinal product which the "corporations within the European Economic Community (EEC)" have adopted. We quote from the "Food Drug Cosmetic Law Journal," of August 1975, Vol. 30, No. 8, at page 485:

> Medical product is defined as meaning:
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> (1) any substance or combination of substances presented for treating or preventing disease in human beings or animals;
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> (2) any substance or combination which may be administered to human beings or animals; or
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> (3) any substance or combination of substances which may be administered to human beings or animals with the view of making medical diagnosis or restoring, correcting or modifying physiological functions in human beings or animals.

We are therefore satisfied that in the instant circumstances the claims are directed to a form of "medicinal treatment" in the preservation of the health of animals.

Of importance then is the decision in Tennessee Eastman v Commissioner of Patents, supra, in which the Supreme Court of Canada considered a surgical method for joining wounds in living animals. Mr. Justice Pigeon made the following statement:

> Just as in the case of "art", the scope of the word "process" in section 2(d) is somewhat circumscribed by the provision of section 28(3) excluding a "mere scientific principle or abstract theorem". There is no question here of the alleged invention being such. It is clearly in the field of practical application. In fact, as the record shows, the "invention" essentially consists in the discovery that a known adhesive substance is adaptable to surgical use. In other words, the subject-matter of the claimed invention is the discovery that this particular adhesive is non-toxic and such that it can be used for the surgical bonding of living tissues as well as for a variety of inert materials. In this situation, it is clear that the substance itself cannot be claimed as an invention and the appellants have not done so. Their claims are limited to a method, i.e., process, which in this case is nothing else than a new use for a known substance. The sole question is therefore whether a new use for surgical purposes of a known substance can be claimed as an invention... Is such a method an "art" or "process" within the meaning of the definition of "invention"?

> It is clear that a new substance that is useful in the medical or surgical treatment of humans or of animals is an "invention". It is equally clear that a process for making such a substance also is an "invention". In fact, the substance can be claimed as an invention only "when prepared or produced by" such a process. But what of the method of medical or surgical treatment using the new substance? Can it too be claimed as an invention? In order to establish the utility of the substance this has to be defined to a certain extent. In the case of a drug, the desirable effects must be ascertained as well as the undesirable side effects. The proper doses have to be found as well as methods of administration and any counter-indications. May these therapeutic data be claimed in themselves as a separate invention consisting in a method of treatment embodying the use of the new drug? I do not think so, and it appears to me that section 41 definitely indicates that it is not so. (emphasis added)

It is clear from the above that a method of medical treatment cannot be claimed as an invention.

The applicant referred to two previous decisions of the Board relating to "methods of improving the rate growth of animals." These decisions were made prior to the Tennessee Eastman v Commissioner of Patents (S.C.) decision, supra. Furthermore, there is more evidence available to the Board, as noted above, with regard to the reasons for the increase in growth in animals when antibiotics are added to their food. For example, we quote from the book, "Microbiology" supra: "The antibiotics may destroy bacteria and other intestinal parasites that cause subclinical disease and retard growth and development."

In summary, we are satisfied that there is no second invention over that allowed in the parent, and that the claims were also properly refused on the ground that they relate to a form of "medical treatment," and should not, in our view, be claimed as a process apart from the drug itself. (Vide, Tennessee Eastman v Commissioner of Patents, supra.) As there is no further patentable subject matter in the application we recommend that the claims and the application as a whole be refused.

J.F. Hughes,
Assistant Chairman
Patent Appeal Board

I concur with the recommendations of the Patent Appeal Board. Accordingly, I refuse to grant a patent. The applicant has six months within which to appeal this decision under the provisions of Section 44 of the Patent Act.

J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec

this 29th day of September, 1976

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