

COMMISSIONER'S DECISION

NON-STATUTORY SECTIONS 2 & 41: Medical Treatment In "Strict Sense".

Treatment of animals including humans using a substance within the judicial meaning of "medicine" under Section 41(1) is not claimable as an invention under the Act. No distinction is made between medical treatment of humans and animals which would tend to overbear the implications of Section 41. A substance intended for medicinal or surgical purpose is clearly an invention in the field of "practical application", whether or not apposite to use in "trade or commerce".

FINAL ACTION: Affirmed.

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This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated May 30, 1972 on application 950,330, Cl. 167 - Sub. Cl. 265. The application was filed on January 20, 1966 in the name of Paul A. Barrett and is entitled "Veterinary Pharmaceutical Formulations And Method of Treatment of Animals".

This application relates to a pharmaceutical composition and to a method of treating animals (excluding humans) with the composition. Only the method of "treating animals" is under consideration in the Final Action.

In the prosecution terminated by the Final Action the examiner refused claims 6 and 7 for reasons that a method of medical treatment, even if applied to animals does not constitute patentable subject matter under Section 2 of the Patent Act.

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

The rejection of claims 6 and 7 is maintained and the reasons for such rejection is that a method of medical treatment even if applied to sick animals does not constitute patentable subject matter under Section 2(d) of the Patent Act, since a medical treatment does not constitute a new manufacturing process and does not result in a new and different commercial product. Furthermore it is up to a practitioner of medicine

in general, or verterinary medicine, to detect and decide if the ailing animal is suffering from anaplasmosis and then decide accordingly, which of the ways and methods for treatment available to him is the best recommended in any particular case at hand.

The applicant in his response, dated November 29, 1972 to the Final Action, removed objectionable claims 6 and 7, and requested allowance of the application.

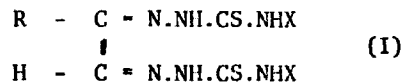
On December 7, 1972 the applicant added claims 15 and 16. These claims are the same as rejected claims 6 and 7, except they excluded humans from the treatment. The applicant presented no arguments to support his contention that claims 15 and 16 were allowable, however, this was Patent Office policy at that time.

Essentially the alleged invention is the application of a composition, comprising an effective amount of a physiologically active agent and an acceptable carrier, to animals (excluding humans). It is the use or application of this composition which was refused in the Final Action, because it is "a method of medical treatment."

The question to be decided is whether a new use of the new composition of claim 1, for medical purposes, may be claimed as an invention.

Claim 1, which was not refused in the Final Action, reads:

A veterinary pharmaceutical formulation which contains a compound of formula (I)



wherein R is a hydrogen atom or a benzyl group or an alkyl or hydroxyalkyl group of 1 to 4 carbon atoms and X is a hydrogen atom or a methyl, ethyl or methoxymethyl group together with a carrier therefor.

Amended claim 15, filed pursuant to the Final Action, relates to "a method of using the composition of claim 1," and reads:

A method of treating animals, excluding humans, suffering from anaplasmosis which comprises the administration of a compound of formula (I) as defined in claim 1 to the infected animal.

A point of interest is that on October 6, 1972 the Commissioner of Patents issued a decision in which a method of medical treatment of animals excluding humans was allowed. This decision was based on the consideration of what appeared as the state of the law at that time, with reference to the Exchequer Court decision in Tennessee Eastman Co. v. The Commissioner of Patents (1970) 62 CPR 117 wherein Kerr J. after an exhaustive review of authorities stated:

In my view the method here does not lay in the field of manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject matter for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of subsection (d) of section 2 of the Patent Act. (emphasis added).

This decision relates to "a new use for esters of a-cyanoacrylic acid and more particularly to a surgical method of joining tissue surfaces through the use of such esters as adhesives," which was appealed to the Supreme Court. It is the S.C.C. decision which is the basis for the present Final Action.

Of importance, therefore, in this determination is the rationale of the Supreme Court in Tennessee Eastman v. Commissioner of Patents (1973) 8 C.P.R. 202 at pages 206 and 207, wherein Pigeon J. stated:

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)

Also of interest is the reference by the S.C.C. in Tennessee Eastman v. Commissioner of Patents, supra, to the Schering AG's application 1971 RPC 337, a decision dealing with a method of contraception, citing the conclusion of the Patent Appeal tribunal at page 345 as follows:

Although, however, on a full consideration of the matter it seems that patents for medical treatment in the strict sense must be excluded under the present Act, the claims the subject of the application do not appear to fall within this prohibition and, on the law as it stands today, they should at least at this stage in our judgement, be allowed to proceed.... (Emphasis added by the Court)

Accordingly, it is clear firstly, that a new use for surgical or medical purposes of a "known" substance is an art or process within the meaning of Section 2 since it has a practical application, and secondly that the medical or surgical use of a "new" drug governed

by Section 41(1) cannot be claimed as a separate invention from the drug itself. However, in either situation it may be deduced that claims for "medical treatment in the strict sense" are excluded from protection under the Patent Act.

The specific question which must be decided is whether the application of the composition of claim 1 to animals (excluding humans) constitutes "medical treatment" within the meaning of Tennessee Eastman v. Commissioner, supra.

In Imperial Chemical Industries Ltd. v. Commissioner of Patents (1967) 51 C.P.R. 102 at pages 105-119, there was a lengthy discussion about the meaning of "medicine" as used in Section 41(1) of deciding whether an anaesthetic is a substance for use as a medicine. The Exchequer Court decided at page 105 that the term "medicine" should be interpreted in its ordinary sense. In reaching that conclusion it considered a number of dictionary definitions (found at pages 108-119). In general, it is noted that "medicine" is defined as "a substance used for the treatment or prevention of disease." The court held that "Halothane" which is an "inhalation anaesthetic," is a substance intended for "medicine" within the meaning of Section 41 of the Patent Act. The British Medical Dictionary defines a "drug" as "any chemical substance, synthetic or extracted from plant or animal tissue and of known or unknown composition, which is used as a medicament to prevent or cure disease."

But in Tennessee Eastman v. Commissioner (S.C.C.), supra, Pigeon J. at pages 208-209 indicates a limitation to the breadth of the definition of medicine. He referred with approval to the Schering decision, which held that "a method of contraception involving the use of a drug" is not a "medical treatment in the strict sense." Pigeon J. also referred to the Swifts and Company's application

(1962 R.P.C. 37) and National Research Development Corporations' application (1961 R.P.C. 134) cases as being exceptions to methods of treatment in general. Swift's application dealt with a method of tenderizing meat by injecting enzymes into the animal before slaughtering. The N.R.D.C.'s application covered a method of eradicating weeds.

Therefore, considering the full import of the meaning of "medicine" as brought out above, the use to which the applicants puts the composition should, in our view, be considered a "medical treatment in the strict sense," as contemplated by the S.C.C. in Tennessee Eastman v. Commissioner, supra.

The last determination we must make is whether medical treatments as defined by the Supreme Court in Tennessee Eastman v. Commissioner of Patents, supra, include the treatment of animals as well as humans.

As previously mentioned the Exchequer Court in Tennessee Eastman Co. v. Commissioner of Patents, supra, recognized a difference between methods applied to humans and those to animals. It concluded that treatment of humans does not produce a result related to trade or commerce. Particular emphasis was placed on trade and commerce and the admission of the existence of two possible entities, namely medical treatment relating to humans and medical treatment relating to animals.

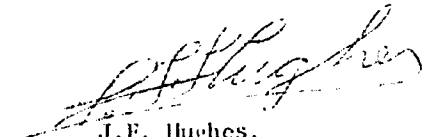
In the Supreme Court, however, Pigeon J, made no specific mention of trade and commerce, but (at page 206) concluded that the alleged invention "...is clearly in the field of practical application. In fact, as the record shows, the "invention" essentially consists in the discovery that a known adhesive substance is

adaptable to surgical use." Pigeon J. further made no distinction between animals and humans when, at page 206, he stated: "It is clear that a new substance that is useful in the medical or surgical treatment of humans or of animals is an invention," and further that "The sole question is therefore whether a new use for surgical purposes of a known substance can be claimed as an invention.... I do not think so, and it appears to me that Section 41 definitely indicates that it is not so."

If Section 41 of the Patent Act is intended to cover "foods and medicines" in relation to both humans and animals (See American Home Products v. Commissioner of Patents Supreme Court of Ontario, Dec. 18, 1969), it follows then that no distinction is to be made between medical treatments for humans and those for animals which would tend to overbear the implications of Section 41 of the Patent Act.

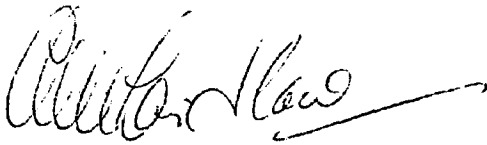
In the circumstances, therefore, the Board is satisfied that "medical treatment in the strict sense" whether applied to humans or to animals, cannot be claimed as an invention under the provisions of the Patent Act.

The Board therefore recommends that the decision of the Examiner to refuse claims to "medical treatment" be affirmed.

  
J.F. Hughes,  
Assistant Chairman,  
Patent Appeal Board.

I concur with the findings of the Patent Appeal Board. Accordingly,  
I refuse to grant a patent on the subject matter of amended claims  
15 and 16. The applicant has six months within which to appeal  
this decision under the provision of Section 44 of the Patent Act.

Decision accordingly,

A handwritten signature in dark ink, appearing to read 'A.M. Laidlaw', with a long horizontal flourish extending to the right.

A.M. Laidlaw,  
Commissioner of Patents.

Signed and dated in  
Hull, Quebec this  
22nd day of May, 1974

Agent for Applicant

Alan Swabey & Co.