COMMISSIONER'S DECISION

UNSTATUTORY - Ss. 2 and 41(1): Medical Treatment of Animals Including Humans.

Medical treatment in the strict sense, as using a medicinal for the treatment, curing and prevention of disease, is an invention that cannot be claimed under the provisions of sections 2 and 41(1) of the Act; even though such new use of a known substance is an art or process within the meaning of S. 2 as having "practical application". No distinction is made between the treatment of humans and animals which would overbear the implications of Section 41.

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 June 19, 1973 on application 947,803. This application was filed on December 14, 1965 and refers to a "Membrane Penetrant Composition Comprising Dialkyl Sulfoxides, Process for Preparing Same and Method of Using Same." The Patent Appeal Board conducted a Hearing on March 27, 1974 at which Mr. R. Fuller represented the applicant.

The application relates to a tissue penetrant composition (an effective amount of a physiologically active agent, an effective amount of dimethyl sulfoxide and an acceptable aqueous diluent) and the application of this composition to animals including humans.

In the prosecution terminated by the Final Action the examiner refused claims 8 to 16 in that methods of medical treatment do not constitute patentable subject matter under Section 2 of the Patent Act.

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

> The unpatentability of this type of claim (method of medical treatment) relies on the Supreme Court decision in "Tennessee Eastman Co. vs. The Commissioner of Patents" handed down by the Supreme Court on December 1972. Mr. Justice Pigeon in answer to the question on page 6 (last paragraph)
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> "is such method an "art" or "process" within the meaning of the definition of "invention"?"
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> concludes that methods of medical treatment are not processes within the meaning of "invention" as defined in Section 2 of the Patent Act as 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"...."

Applicant in his letter of May 2, 1973 requests a final action be issued under Rule 46 on this application "so that this matter can be once again considered by the Patent Appeal Board to see if they agree with the Examiner's view that the Supreme Court decision has a significant effect on a policy that should be followed by the Patent Office".

The main difference between the Exchequer Court and the Supreme Court decisions is not that the Patent Office was supported in one and not in the other. The Patent Office was supported in both Courts.

This application has inserted a limitation in the method of medical treatment claims to exclude humans, where the claims in the Tennessee case did not exclude humans and in this respect differ from the claims in the present application.

Both Tennessee and this application disclose methods of medical treatment which are capable of use in the treatment of both people and animals.

The chief difference between the two decisions is that the Exchequer Court decision emphasized a ground for refusal that was scarcely mentioned in the Supreme Court decision. It is whether this ground still applies after the Supreme Court ruling that is questioned herein and is now discussed in details.

The applicant in his response dated October 31, 1973 to the Final Action stated (in part):

> As has previously been argued in this case, applicants do not consider that these claims relate to a method of medical treatment so that they constitute subject matter which is unpatentable under Section 2 of the Patent Act. On the other hand it is the Examiner's position that claims 8 to 16 are unpatentable in view of the Supreme Court decision of December 1972 in Tennessee Eastman vs The Commissioner of Patents....
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> Presumably therefore it is the Examiner's contention that the Supreme Court decision in Tennessee Eastman Company vs The Commissioner of Patents establishes, beyond any doubt, in contrast to the corresponding Exchequer Court decision that claims, such as claims 8 to 16 which appeared in this application prior to the present amendment, are unpatentable under Canadian Law. Applicants respectfully submit that this is not so.
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> ...
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> Applicants must conclude therefore that it is now established by this decision that the discovery of a second use for an old substance if that second use involves clinical data per se cannot form the subject of a patent if it provides "an easy way out of the restriction in Section 41(1)". A similar line of reasoning is presumably followed in the Commissioner of Patents vs Farbwerke Hoechst 41 C.P.R. 9 (1964), where it was held that a second patent could not be granted for a pharmaceutical composition containing the antidiabetic agent tolbutamide when a patent had already been granted for tolbutamide itself; and in Gilbert vs Sandoz 64 C.P.R. 14, and affirmed by the Supreme Court as reported in 8 C.P.R. (2d) 210, where the Court declared claims

to a mere admixture of an active substance and a carrier are invalid when present in the same patent as claims to the active substance alone. All such claims would presumably provide "an easy way out of the restriction in Section 41(1)". In the present case, no such problem exists as the inventor is the first to formulate certain compositions containing dimethyl sulphoxide giving practical utility to its newly discovered unusual and possibly unique physiological action. As dimethyl sulphoxide is a substance which has been known to chemists for many years, no patent exists containing claims to dimethyl sulphoxide per se based on a medical or any other use, which could be governed by the provisions of Section 41(1). The present invention therefore of new and useful multi-component compositions containing dimethyl sulphoxide and a method employing such compositions cannot be said to be "an easy way out of the restriction of Section 41(1)" as Section 41(1) is not applicable in the present case particularly as the present application is clearly directed to a further invention over and above that of the substance (dimethyl sulphoxide) itself.

Essentially the alleged invention is the application of a composition, comprising an effective amount of a physiologically active agent, an effective amount of dimethyl sulfoxide and an acceptable aqueous diluent, to animals including humans. The composition may be administered by various routes including oral, topical and injectable. 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 tissue penetrant composition which comprises an effective amount of a physiologically active agent, said agent being a physiologically active steroid, antineoplastic agent, antigen, antibacterial agent, antihistaminic agent, neuropharmacologic agent, anti-inflammatory agent, anticoagulant, vasodilator, ultra-violet screening agent, diagnostic dye, diagnostic radiopaque agent, vitamin, insulin, general anaesthetic, local anaesthetic, or analgesic, an effective amount of pharmacologically acceptable grade of a dimethyl sulfoxide and a pharmaceutically acceptable aqueous diluent or carrier.

Amended claim 8, filed pursuant to the Final Action, relates to "a method of using the composition of claim 1," and reads:

> A method for increasing the tissue penetration of a physiologically active agent selected from the group consisting of physiologically active steroids, antineoplastic agents, antigens, anti-unicellular micro-organism agents, antihistaminic agents, neuropharmacologic agents, anti-inflammatory agents, anticoagulants, vasodilators,

> ultraviolet screening agents, diagnostic dyes, diagnostic radiopaque agents, vitamins, insulins, general anaesthetics, local anaesthetics and analgesics which comprises applying said physiologically active agent concurrently with dimethyl sulfoxide and a pharmaceutically acceptable aqueous diluent or carrier.

It is observed that claim 8 above is broader in scope than the claims under rejection in that it is not restricted to "animals excluding humans."

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 of 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"?
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> 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. (underlining 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 appli-

cation", 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 applicant has argued, particularly at the Hearing, that "the dimethyl sulfoxide itself is not a medicine," and that "the rejected subject matter is not restricted to a medical treatment." We do have on record in TAPPI, June 1965, at page 1 the statement that: "DMSO has been shown to have value as an analgesic, anti-inflammatory agent, diuretic, collagen plasticizer, bactericide fungicide...." In our view, however, there is no need to consider this point at length, for it is settled law that what is claimed must be construed as a whole. We must consider whether the compositions made up of dimethyl sulfoxide and the physiologically active agents of claim 1 are medicines. More specifically it must be decided whether the application of the composition to animals (including 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 118-119). 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.

In the present disclosure, some of the applications in which the composition of claim 1 are used are: penetration of penicillin for treatment of an infected ingrown toe nail; penetration of local anaesthetics to relieve pain in the lumbascaral area of the body; chematherapeutic agent penetration to treat malignancy; insulin penetration for the treatment of pancreatectomy in dogs; and insulin penetration for diabetic treatment. These treatments allegedly produce excellent results, and there is no doubt that the composition is used for the "curative treatment of disease."

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.

The applicant also referred to previous decisions of this Board, in particular that for: "Promoting growth in ruminant animals" and that for "Method of testing body fluids or tissue," in support of his contention that the present subject matter is allowable. Those decisions, however, are distinguishable since they involved no treatment of a disease; in other words there was "no medical treatment in the strict sense."

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 recommends that the decision of the examiner to refuse the subject matter of claims 8 to 16 be affirmed. It follows that proposed claims 8 to 17, which are broader in scope than the rejected claims, should also be refused.

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 claims 8 to 16 or the proposed claims. The applicant has six months within which to appeal this decision under the provision of Section 44 of the Patent Act.

Decision accordingly,

A.M. Laidlaw,
Commissioner of Patents.

Signed and dated in
Hull, Quebec this
14th day of May, 1974

Agent for Applicant

Smart & Biggar