

COMMISSIONER'S DECISION SUMMARY

C.D. 1213Application No. 559,960 (K11)

Claims rejected as being directed to methods of medical treatment

The application contained claims which were directed to methods of ameliorating the adverse effects of aging in mammalian cells by contacting the cells with a composition containing an effective amount of a 6-(substituted amino)purine cytokinin. The claims were rejected by the examiner on the grounds that they claimed methods of medical treatment. The Board recommended that the rejection be withdrawn since such methods are not methods of medical treatment in the strict sense as defined by the courts.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 559,960, having been rejected under Subsection 47(2) of the Patent Rules, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

Agent for the Applicant

MacRae & Co.
P.O. Box 806, Station B
Ottawa, Ontario
K1P 5T4

This decision deals with a request that the Commissioner of Patents review the Examiner's Final Action on patent application number 559,960 (Class 167-220) which was filed on February 26, 1988. The Applicant is Senentek PLC, assignee of inventor Suresh I.S. Rattan and the invention is entitled "METHOD AND COMPOSITION FOR AMELIORATING THE ADVERSE EFFECTS OF AGING". The Examiner in charge issued a Final Action on November 27, 1992 rejecting claims 1, 3 to 9 and 11 to 13 and the Applicant replied on May 26, 1993 requesting that the refusal be reviewed by the Commissioner of Patents.

The invention is directed to a methods and compositions for ameliorating the adverse effects of aging in mammalian cells without increasing the cells' growth rate or total proliferative capacity. Thus 6-(substituted amino) purine cytokinins, including kinetin, have been discovered to ameliorate the adverse effects of aging of such cells both in culture and in vivo. Among the preferred applications of the invention are the preservation of the health of mammalian cells in culture and, by application to human skin of kinetin-containing lotions, ointments or creams, the health and youthful appearance of the skin.

The application contains 19 claims, with claims 1 to 13 directed towards methods for ameliorating the adverse effects of aging on mammalian cells and claims 14 to 19 directed towards compositions for the same purpose with claims 2 and 10 being limited to the treatment of cultured mammalian cells in vitro. In his Final Action the Examiner rejected claims 1, 3 to 9 and 11 to 13 on the grounds that they were directed to unpatentable subject matter in that they claimed methods of medical treatment. In developing his rejection of the claims the Examiner stated that:

The refusal of claims 1, 3 to 9 and 11 to 13 is maintained. The rest of the claims are allowable.

The applicant's arguments against the rejection of claims 1, 3 to 9 and 11 to 13 are noted, however it was decided that they do not overcome the objection.

The applicant first argues that any method which is not a method of medical treatment can be construed as a method of medical treatment. He provides 2 examples of such process to illustrate his point. One example is to a method of coating a seed for the purpose of producing a healthy plant and thus better crop yield and the other to starting a car in winter to heat it. The applicant argues both processes eventually lead to the end effect which will improve the health of a person, namely the improved nutritional health in the former case and protection from hypothermia in the latter case. The reason for these types of processes being non-medical is because the primary results of these methods are not medical in nature. This argument not only does not overcome the objection, but also enforces the argument that the process in question is a method of medical treatment. The primary effect of applying a 6-(substituted amino) purine cytokinin is for restoring or maintaining health of the skin. The cosmetic effect is the secondary effect of the process, namely, the result of healthier skin.

The applicant provides further arguments by providing various definitions of a method of medical treatment and on page 3 he poses a question.

"Is the method in question directed to the management or care of a patient for the purpose of combatting any deviation from or interruption of the normal structure or function of any part, organ or system of the body?"

He further argues that if the answer to the above question is "yes", it is clearly a method of medical treatment

The answer to the above question in the examiner's view is clearly "yes" and therefore it is a medical treatment. The process in question is primarily for maintaining or bringing back the health of the skin therefore it is the management for the purpose of combatting any deviation from the normal structure of the body

Claim 1 which is representative of the claims under rejection is reproduced below:

1 A method for ameliorating the adverse effects of aging on mammalian cells, comprising contacting mammalian cells with a cosmetic composition that contains an effective concentration of a 6-(substituted amino)purine cytokinin, wherein the cells are on the surface of a living animal, and the concentration is sufficient to ameliorate the adverse effects of aging of said cells, whereby the rate of development of characteristics of said cells that are associated with cellular aging is reversed or slowed, and the growth rate and total proliferative capacity of the cells subsequent to said contacting is substantially the same as prior to said contacting

The question before the Board is therefore whether or not claims 1, 3 to 9 and 11 to 13 claim methods of medical treatment and are thus directed to unpatentable subject matter.

The Applicant in its response has argued that the claims at issue are not directed to methods of medical treatment as that term is defined in most medical dictionaries. Thus a suitable definition of "medical treatment" according to the Applicant is a method pertaining to the art and science of the diagnosis of disease and the management and care of a patient for the purpose of combatting disease or disorder. The Applicant submits that the operative words in the derived definition are disease and disorder where disorder is a derangement or abnormality of function. That which combats disease or like biological abnormalities is a method of medical treatment. In the absence of disease or disorder, a method of treatment is non-medical.

In explaining its position the Applicant stated, at page 3 of its submission, that:

The applicant submits that aging is not a disease or disorder. According to Dorland's Illustrated Medical Dictionary, aging is gradual change which does not result from disease or other gross accidents. The applicant submits that aging is undeniably a normal, natural process. In human beings, this process will eventually result in wrinkling of the skin. Such wrinkles are also not a disease or disorder. Accordingly, a method

of ameliorating the adverse effects of aging, a method which reduces the wrinkling of the skin, is a method directed to the treatment of a normal human condition and not a method directed to the treatment of a disease or disorder. Such a method is therefore not a method of medical treatment.

In considering this matter the Board has studied several prior court decisions which bear on related subject matter. Firstly in the Imperial Chemical Industries Ltd. v. Commissioner of Patents decision [9 C.P.R. (3d) 289] quoted by both the Examiner and the Applicant in earlier prosecution the invention related to a method of removing dental plaque or stains, including tobacco stains, from human teeth by applying to the teeth an aqueous composition containing lanthanum cations in the form of a dissolved water-soluble salt in a defined concentration. The Commissioner found that the method was a method of medical treatment on the grounds that the removal of plaque and stains from teeth removed potential breeding spots for bacteria leading to the improved health of the user. On appeal to the Federal Court of Appeal Heald J. ruled that the Commissioner had made no error in law in holding that the method was a method of medical treatment stating, at page 293, that:

The disclosure of the invention emphasizes two main benefits from the invention

- (i) the cosmetic value, and
- (ii) the reduction in the incidence of caries and/or periodontal disease

The record shows that only a very small percentage of the population in industrialized countries is free from caries or periodontal disease (in the U.S.A., approximately 0.1% of the population). On this basis, I think there was sufficient evidence for the commissioner to conclude that a leading function of the invention was medical. I also think that it is possible to have more than one main purpose in a product. The evidence here suggests that this product had two main purposes, one medical and the other cosmetic. Accordingly, I see no error in law by the commissioner in characterizing the invention as having a medical function simply because it may also have another leading function, namely a cosmetic one.

In other words Heald J. found no reason to disturb the commissioner's finding of fact that the method claimed in I.C.I. was a method of medical treatment and therefore unpatentable.

In the Supreme Court decision in Tennessee-Eastman v. Commissioner of Patents 62 C.P.R. 117; 8 C.P.R. (2d) 202 the Court decided that a method for bonding the surfaces of wounds or incisions with specialized adhesives was a method of medical treatment and consequently unpatentable. In the course of its review the Court considered the U.K. decision in Re: Schering A.G.'s application (1971) R.P.C. 337 which dealt with a method of contraception by means of a gestagen. With regard to the Schering decision the Court stated, at page 209, that:

It might be noted that in the latest reported case brought to our attention, *Re Schering A.G.'s Application*, [1971] R.P.C. 337, a case dealing with a method of contraception by means of gestagen, the conclusion of the Patents Appeal Tribunal was at p 345

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 judgment, be allowed to proceed. As *Swift's Application* (1962) R.P.C. 37 in the Divisional Court of the Queen's Bench Division clearly established, the Office and the Patents Appeal Tribunal are at this stage not deciding the question of "actual patentability", as the phrase was used in that case, and unless there is no reasonable doubt that a manner of manufacture is not being claimed or the application is plainly without justification, it is their duty to allow the claim. The applicants will then have the opportunity in due course, if the matter arises, of having "actual patentability" decided in the High Court

(Emphasis added)

This decision therefore stands for the proposition that it is only methods which are methods of medical treatment in the strict sense that are unpatentable and therefore that methods which are not directed to treating pathological or disease conditions are patentable. This reasoning of the Supreme Court was recognized by the Commissioner of Patents in the decision in Re Application for Patent of Goldenberg 22 C.P.R. (3d) 159 wherein it was stated, at page 169, that:

We believe that the Supreme court in the *Tennessee Eastman* case emphasized by quoting from the *Schering* case, that patents for medical treatment in the strict sense must be excluded under the *Patent Act*

In Goldenberg the invention related to a method of detecting tumours in the human body by the injection of certain radiolabelled antibodies having a high specific activity and high specificity for cancerous tumour cells into the body followed by scanning of the body by a radiation detector to determine the locality of the tumour prior to treatment. The Board's recommendation which was accepted by the Commissioner was that the rejection of the methods as being directed to methods of medical treatment be withdrawn since such methods were not considered to be methods of medical treatment in the strict sense.

Since it is clear from the foregoing that methods of medical treatment in the strict sense, i.e. methods that lead to the prevention or cure of pathological conditions, are not patentable the question then becomes "Are methods of ameliorating the normal effects of aging methods of medical treatment in the strict sense?" There are certain aspects to the present method claims which could lead them to be considered as being directed to methods of medical treatment. Thus it is stated in the application that the applying 6-(substituted amino) purines to skin causes changes in the

metabolism of the skin cells which retard the aging process of the cells. However on the other hand, as the Applicant has pointed out, aging is a natural condition of the human body not a disease so that the method should not be considered as a method of medical treatment since no pathological condition is cured. In considering this question the Board is of the opinion that the methods disclosed in the application are not methods of medical treatment in the strict sense as determined in the Tennessee-Eastman case and should therefore be considered allowable.

In coming to this conclusion the Board was mindful of the test imposed on the Commissioner by section 40 of the Patent Act which was stated in Monsanto Co. v Commissioner of Patents 42 C.P.R. (2d) 161 at page 177 in the following terms:

As this is a matter of general knowledge among scientists, it will be readily apparent to a competent person that if a patent covers only a few of the substances which yield the desired result, all he has to do is to prepare another which will have the same properties. The report of the Board indicates that it is aware of this. However, it gives no indication of the reasons for which it was not satisfied of the soundness of the prediction of utility for the whole area covered by claim 9. Evidence had been submitted in the form of affidavits based on scientific principles, it does not take issue with those principles, it just says "We are not satisfied that this is adequate". In my view this is insufficient because, if accepted, it makes the right of appeal illusory. In this respect it is important to note that s 42 of the *Patent Act* reads

42 Whenever the Commissioner is satisfied that the applicant is not by law entitled to be granted a patent he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of such refusal and of the ground or reason therefor

I have emphasized by law to stress that this is not a matter of discretion the Commissioner has to justify any refusal. As Duff, C J, said in Vanity Fair Silk Mills v Commissioner of Patents, [1938] 4 D L R 657, [1939] S C R 245 at p 246

No doubt the Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation

In other words the Board considers that the Applicant is not by law prevented from obtaining claims for a method of ameliorating the effects of aging on the human skin by the administration of the substances described in the application.

The Board therefore recommends that the rejection of claims 1, 3 to 9 and 11 to 13 be withdrawn and that the application be returned to the Examiner for further prosecution consistent with the recommendation.

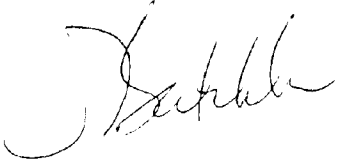


P.J. Davies
Chairman



M. Howarth
Member

I concur with the recommendation of the Board and return the application to the Examiner for further prosecution consistent with the Board's recommendation.



S. Batchelor
Commissioner of Patents

Dated at Hull, Quebec,
this 23 day of Jan/97