COMMISSIONER'S DECISION SUMMARY

C.D. 1209 ....Application No. 532,566 (K11)

Claims rejected as being directed to methods of medical treatment

The application contained claims which were directed to methods of preventing pregnancy in a female mammal by the administration of a luteinizing hormone releasing hormone. 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 The Board recommended that the rejection be withdrawn since such methods are not methods of medical treatment in the strict sense as defined by the courts.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 532,566, 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:

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This decision deals with a request that the Commissioner of Patents review the Examiner's Final Action on patent application number 532,566 (Class 167-192) which was filed on March 20, 1987. The Applicant is The General Hospital Corporation, assignee of inventor William F. Crowley Jr. and the invention is entitled "CONTINUOUS DELIVERY OF LUTEINIZING HORMONE RELEASING HORMONE COMPOSITIONS IN COMBINATION WITH SEX STEROID DELIVERY FOR USE AS A CONTRACEPTIVE". The Examiner in charge issued a Final Action on April 22, 1992 rejecting claims 8 to 13 and the Applicant replied on October 6, 1992 requesting that the refusal be reviewed by the Commissioner of Patents.

The invention is directed to a delivery system and a method useful for preventing pregnancy in female mammals by administering an LHRH composition. The method comprises administering during the entire follicular phase of the menstrual cycle, beginning at the time of menses, an LHRH composition and sufficient levels of an estrogenic steroid to counteract the possibility of side effects which may develop during prolonged therapy with LHRH. Following the follicular phase, at the beginning of the luteal phase, and for the entire course of the luteal phase, the LHRH/estrogenic steroid combination administered during the follicular phase, in combination with a physiological amount of a progestational steroid, is administered.

The application contains 13 claims directed towards a delivery system for preventing pregnancy in a female mammal and to a method of preventing pregnancy in a female mammal. Further claims 14 to 19 directed to the use of an effective amount of a luteinizing hormone releasing hormone composition and an effective amount of an estrogenic steroid for preventing pregnancy in a female mammal were also suggested for inclusion in the application in Applicant's response to the Final Action.

In his Final Action the Examiner rejected claims 8 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 8 to 13 is maintained Claims 1 to 7 are allowable
>
> The applicant in his lengthy argument concludes that the method claimed here is definitely not for the cure, alleviation or prevention of disease, or for restoring health The Office contends that the method in question includes a method of preventing illness. The contraceptive method is used not only to prevent unwanted pregnancy in the ordinary sense but also to prevent the pregnancy of a female for whom the pregnancy brings some physically damaging results This latter subject matter is clearly in the area of preventive medicine

Claim 8 which is representative of the claims under rejection is reproduced below:

> 8 A method for preventing pregnancy in a female mammal, comprising
> (a) administering via a delivery system an effective amount of a luteinizing hormone releasing hormone (LHRH) composition and an effective amount of an estrogenic steroid to said female during the follicular phase of the menstrual cycle, beginning at the onset of normal menses in said female; and
> (b) replacing said first delivery system at the end of said follicular phase with a second delivery system, wherein said second delivery system administers a luteinizing hormone releasing hormone (LHRH) composition, an effective amount of an estrogenic steroid and an effective amount of a progestational steroid to said female during the luteal phase of the menstrual cycle, until the beginning of normal menses in said female.

The question before the Board is therefore whether claims 8 to 13 claim methods of medical treatment and are thus directed to unpatentable subject matter.

The Applicant has argued that in taking his position the Examiner has overlooked (1) the Supreme Court decision in Tennessee-Eastman v. Commissioner of Patents (1973) 8 C.P.R. (2d) 202, (2) the fact that what should be considered is the main or primary use of the product as set forth in the Supreme Court decision in Burton Parsons Inc. v. Hewlett Packard Ltd. (1975) 17 C.P.R. (2d) 97 and (3) that even where pregnancy could have harmful consequences because of some existing disease, pregnancy itself is not a disease.

With respect to the first point the Applicant asserts that the Supreme Court has held in Tennessee-Eastman that a method of contraception is not a method of medical treatment in the strict sense and therefore should be patentable. In Tennessee-Eastman the Supreme Court considered the patentability of a method for bonding the surfaces of wounds or incisions with specialized adhesives. 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, i.e. a method closely similar to the method claimed in the present application. 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)

Whilst the Board does not fully accept the Applicant's contention that the Supreme Court has unequivocally stated that methods of contraception are not methods of medical treatment in a strict sense the Board does note that the quote could at least indicate the Supreme Court's probable position on the patentability of such claims.

The Applicant has also noted that 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 emphasised 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 preventing pregnancy 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 the methods require the administration of chemical substances to a human female under medical supervision, which substances alter the functioning of the body by preventing pregnancy. On the other hand, as the Applicant has pointed out,

pregnancy is a natural condition not a disease so that a method of preventing pregnancy should not be considered as a method of medical treatment since no pathological condition is cured.

The Examiner has further asserted that since the prevention of pregnancy could have beneficial effects to a female if it prevents a pregnancy which could have damaging effects on the female it should nevertheless be considered a method of medical treatment. However the Board accepts the Applicant's argument that it is the main or primary use of the invention which should be considered in determining the invention's patentability [see the decision in Burton Parsons Chemicals Inc. et al. v. Hewlett-Packard (Canada) Ltd. et al. 17 C.P.R. (2d) 97 where Pigeon J., at page 109, stated that:

> I do not find it necessary to reach a firm conclusion on this point because 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 Co. et al. v. Com'r of Patents (1972), 8 C P.R. (2d) 202, 33 D.L.R. (3d) 459, [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. It is obviously a matter of some difficulty to draw the line between what is a medicine and what is only a product apt to be used in connection with medical treatments. In the present case, however, Hewlett-Packard had the burden of proving that the product was a medicine. The evidence has failed to convince the trial Judge that such was the case and I see no reason to disturb his finding

In considering this matter the Board has come to the conclusion that methods of preventing pregnancy 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* not entitled to claims for a method of preventing pregnancy by the administration of the substances described in the application.

The Board therefore recommends that the rejection of claims 8 to 13 be withdrawn, that claims 14 to 19 be entered into the application and that the application be returned to the Examiner for further prosecution consistent with these recommendations.

P.J. Davies
Acting Chairman

M. Howarth
Member

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

S. Batchelor
Commissioner of Patents

Dated at Hull, Quebec,
this 28 day of 10/96