DECISION OF THE COMMISSIONER

IN THE MATTER of a request for review by the Commissioner of Patents of the Examiner's Final Action under Section 46 of the Patent Rules;

And

IN THE MATTER of a patent application serial number 908,951 filed August 7, 1964, by Margaret Treacy for an invention entitled:

PREGNANCY TEST

Agent for Applicant: Gowling, MacTavish, Osborne & Henderson, Ottawa, Ontario.

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action refusing to allow claims 16, 17 and 18 of application 908,951. The request was made in accordance with Section 47(3) of the Patent Rules (prior to amendment by Order-in-Council P.C. 1970-728 effective June 1, 1970).

In the prosecution terminated by the Final Action the Examiner refused to allow the application on the following grounds:

- 1) The subject matter of claims 16, 17 and 18 does not fall within the limits of what may be patented under Section 2(d) of the Patent Act as relating to a testing method for the diagnosis of pregnancy.
- 2) A method for carrying out an analytical test for the determination of pregnancy is not in any way associated with commerce, trade and industry and is contrary to the spirit of the term "working on a commercial scale" referred to in the Patent Act.

The subject matter of the rejected claims 16, 17 and 18 relates to a method for the detection of HCG in urine by mixing the HCG antiserum with the urine to be tested and then mixing the reagent of the invention with the antiserum urine mixture, agitating the mixture and observing it for agglutination of the particles of the reagent.

The examiner took an action in November 17, 1965 in which he stated:

"Claims 16, 17 and 18 are refused as being directed to testing methods for the diagnosis of pregnancy

which do not come within the realm of patentable subject matter".

In a letter dated May 6, 1966, the applicant requested reconsideration of the rejection, stating that claims 16, 17 and 18 fully complied with Section 2(d) of the Patent Act and that they called for definite procedural steps which are to be followed.

In a letter dated June 14, 1966, the Examiner again rejected the claims as relating to a testing method for the diagnosis of pregnancy which is not within the field of inventions as defined in Section 2(d) of the Patent Act, and he also stated that a method for carrying out an analytical test for the determination of pregnancy is not in any way associated with commerce, trade and industry.

The applicant responded in a letter dated December 5, 1966 and attempted to traverse the objection on the ground that claims 16, 17 and 18 come within the fields of invention set forth in Section 2(d) of the Patent Act. A definition of "art" was given and argument presented to show that the method of claims 16, 17 and 18 did come within that definition. Argument was also advanced against the second branch of the rejection.

On February 28, 1968 the examiner rejected claims 16, 17 and 18 in a Final Action in accordance with Section 46 of the Patent Rules on the grounds that the subject matter od claims 16, 17 and 18 does not fall within the limits of what may be patented under Section 2(d) of the Patent Act, and that a method for carrying out an analytical test for the determination of pregnancy is not in any way associated with commerce, trade and industry and is contrary to the spirit of the term "working on a commercial scale" referred to in the Patent Act. The examiner also stated that methods of killing insects, treating liquids to remove bacteria, etc. are of value to the field of economy, whereas information regarding the condition of a human being is the only result of the diagnostic method claimed in the present application.

In a response submitted May 23, 1968, the applicant requested a review of the rejection by the Commissioner of Patents. Applicant argued that there is nothing in Section 2(d) of the Patent Act which requires that an invention, to be patentable, must be capable of being worked on a commercial scale. The applicant referred to Section 67(2)(a) of the Patent Act which by the terminology employed, implies that some inventions are not capable of being worked on a commercial scale.

Section 2(d) of the Patent Act reads as follows:

"Invention" - means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

In my view claims 16, 17 and 18 define a method used in a diagnostic process for determining the presence or absence of pregnancy in a human female and the basis of the rejection, as I see it, is that the examiner considers that the method does not come within the provisions of Section 2(d) of the Patent Act. The second part of the examiner's objection which the agent has identified as being based on the terminology of Section 67(2)(a) of the Patent Act will not be dealt with in detail since I feel that it is not a strong ground on which to base a rejection.

Dealing then with Section 2(d) of the Patent Act the agent has contended repeatedly that the method of the claims in question is new and useful and possesses the added attribute of inventive ingenuity and is therefore patentable. The Patent Office has consistently, over many years, held the view that everything that is new and useful is not necessarily patentable even though inventive ingenuity is present and the restrictions of Section 28(3) do not apply. This view has been supported in a recent Exchequer Court decision, Lawson v. the Commissioner of Patents handed down by Cattanach J. April 17, 1970.

In the <u>Lawson</u> case Cattanach J. said: "I take it as well settled that all new and useful arts and manufactures are not necessarily included in Section 2(d) of the Act."

Cattanach J. went on to discuss the term "manner of manufacture", which is used in the English, Australian and New Zealand statutes, in relation to the words "art, process, machine, manufacture or composition of matter" which appear in Section 2(d) of the Patent Act, and concluded that both groups of words are simply different ways of expressing the same ideas. He went on to express the view that:

"Mamufacture" connotes the making of something. Thus it is seldom that there can be a process of mamufacture unless there is a vendible product of the process. It must accomplish some change in the character or condition of material objects.

In the present case I fail to see how claims 16, 17 and 18 can be held to define a manner of manufacture. The method involves treating urine with reactants under specified conditions and observing the appearance of the resulting mixture to determine which of two conditions exists. Thus the result of the method is merely a determination by visual observation of the presence or absence of HCG in the urine being tested. In my view this is not a "vendible product of the process" as contemplated by Cattanach J. in the above quotation.

I find therefore that the method claims 16, 17 and 18 do not set forth an invention within the definition of Section 2(d) of the Patent Act.

R.E. Thomas, Chairman, Patent Appeal Board.

I concur in the findings of the Patent Appeal Board and uphold the examiner's rejection of claims 16, 17 and 18.

Decision accordingly,

A.M. Laidlaw, Commissioner of Patents

Dated at Ottawa, this 26th day of October, 1970.