

IN THE CANADIAN PATENT OFFICE
DECISION OF THE COMMISSIONER OF PATENTS

Patent application 502,082 having been rejected under Rule 47(2) of the Patent Regulations, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has consequently been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the ruling of the Commissioner are as follows:

Agent for Applicant

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COMMISSIONER'S DECISION SUMMARY

C.D. 1172... App'n 502,082

(B00), (J00)

Indefiniteness of Claims and Lack of Industrial Value

Although the claims include " a heart straining maneuver", the apparatus claimed is not dependent upon this maneuver and the mention of the maneuver in the claims does not render them indefinite. Furthermore, the assessment of diagnostic methods should be that the methods, and their results, have value to the community to which they are addressed, be reproducible by anyone skilled in the art, and be capable of allowing a practitioner to derive some economic benefit, rather than the utilization of pure commercial value. Rejection withdrawn.

This decision deals with the applicant's request for review by the Commissioner of Patents of the final action on application No. 502,082, entitled "Evaluating Heart Mechanical Performance", Class 326-13.5, filed February 18, 1986. The inventor is Kevin M. McIntyre. The examiner issued a final action on May 11, 1990 refusing to allow the application. An oral hearing was held on January 6, 1992, and arguments were presented by the applicant's patent agent, Mr. R. Mitchell.

The application is directed to an apparatus and method for evaluating a patient's heart function by monitoring the change in arterial pulsations while the patient performs a heart straining maneuver.

In his final action, the examiner rejected all of the claims in the application as being indefinite, and lacking in industrial and commercial value. The following are excerpts from the examiner's action and the applicant's response.

As to his first grounds of rejection, for indefiniteness, the examiner said:

In detail, claim 1 is objectionable because the clause "means for detecting the change..." relies upon the implied method step of making "a heart straining maneuver" which of course cannot be written as a piece of apparatus because it must be either the making of a voluntary effort on the part of the patient or else some action on the part of the operator of the method, ...

Similar objections apply to the process claims; the indefiniteness takes another form in that claims 4 and 5 are directed to "evaluating the mechanical condition of a heart" by "detecting (a) pulse signal" i.e. without even "a heart straining maneuver"... Formally stated, the promise of the preamble is not met by the scope of the claimed steps. Indeed, the steps specifically claimed are little more than those of taking a reading of blood pressure.

In his written response, Mr. Mitchell argued against the rejection on indefiniteness as follows:

... the Examiner states that claim 1 is objectionable because it relies on an implied method step of making "a heart straining maneuver". The applicant strenuously rebuffs this objection. The claims define a structure which is clearly set out without relying on the method of making a heart straining maneuver. The fact that this apparatus can be used for detecting different pulse signals coming from a patient at different stages of activity does not make the

apparatus dependent on the heart straining maneuver. The apparatus must be taken for itself, and the elements recited in a claim must be considered on their face value. Claim 1, particularly as submitted in the new set of claims, is clearly definite in reciting the combination of structural elements, and the fact that it may refer to elements extra the apparatus is merely to clarify the function of the apparatus.

... the Examiner objects to claim 4 as being directed to an evaluation of the mechanical condition of a heart and that it is only in claim 7 that a heart straining maneuver is introduced. In fact, claim 4 describes the steps of providing a pulse signal by placing pressure sensitive transducing means for providing an electrical signal representative of pressure in contact with the skin of a patient while applying a further step of applying pressure at least in part through the pressure sensitive means to adjacent skin at controlled pressure within the range of at least just above the diastolic pressure of said patient and a pressure of substantially half of said diastolic pressure and then detecting the pulse signal. Surely this claim fulfills the promise of the preamble of the claim, that is, to evaluate the mechanical condition of a heart. What is claimed in claim 4 of the present set of claims is not merely the taking of a reading of blood pressure as suggested by the Examiner, but the taking of the arterial pulsation and applying pressure at a controlled pressure within a particular range which is at least just above the diastolic pressure of the patient and a pressure substantially half the diastolic pressure.

The examiner's second rejection was for a lack of industrial or commercial value:

The basic objection to the process claims is that because they must essentially be practised upon an individual body, they therefore cannot define an industrial process. The result, an individual whose heart performance is evaluated, is not a marketable product.

Further even a non-invasive "heart straining maneuver" process step requires some degree of skill and judgement on the part of the operator, whether he be a physician or a trained technician. The inventor himself will be aware that the Valsalva manoeuvre specified in claim 8 is contraindicated for patients suffering from infection of the upper air passages such as rhinitis, sinusitis and the like.

Flowing from these considerations of claimed process details any economic result (or any money changing hands) will be in the nature of a fee for an individual personal service rendered and the process, in total, cannot be called "work on a commercial scale" without gross distortion of language.

From these somewhat semantic considerations flows a commonplace objection, in that the claimed process or method cannot yield the 100% reproducibility required of a patentable process. The starting material, being physiological, is not of the same uniform quality of, say, feedstock for a pulp mill. Thus the step of "subjecting the patient to a heart straining maneuver" deemed essential for "evaluating the mechanical condition of a heart" will require judgement in choice and time and will be entirely unsuitable for some patients.

In response, Mr. Mitchell countered, in part, by saying:

... the Official Action states that the method claims lack industrial value... This question of the method or process lacking industrial value or having any economic result for working on a commercial scale is not understood. The claims must have utility, in an economic sense, and they do. It has been accepted and the Office has been directed by the Courts to the effect that diagnostic methods are patentable under Section 2 of the Canadian Patent Act. As recently as in Re Application for Patent Goldenberg, the Commissioner of Patents rendered a decision on May 13, 1988 reversing the Examiner's objection to what was essentially a diagnostic method for detecting cancerous tumors in the body by injecting a certain type of antibody substances.

The operating of the diagnostic method will require some skill, but this is no more than skill of the "person skilled in the art" to which the specification is addressed. Any timing or other requirements as taught in the specification are clearly 100% reproducible, and the results of the diagnostic tests will, of course, vary depending on the physiological condition of the patient being tested.

... the Examiner refers to comparing the starting material of a process with the uniform quality of feedstock for a pulp mill. Surely the Examiner does not seriously think that feedstock for a pulp mill has uniform quality. Tests must be made constantly to determine the relative quality of the feedstock to then

adjust the process and the equipment. However, a diagnostic or testing method within a pulp mill will be constant; only the results will differ. Likewise, the diagnostic method as applied to a human patient will be constant and reproducible, but the results will vary.

The task before the Board is to decide if the claims to the apparatus and method are framed in a definite manner as defined in Section 34(2) of the Patent Act, R.S.C 1985, c. P-4; and if the claimed method has industrial value.

The Board must then look to the claims for a better understanding of the applicant's invention. Claims 1 and 9 of the newly submitted set of claims read, respectively:

Apparatus for evaluating the mechanical condition of a heart of a patient having skin, comprising, pressure sensitive transducing means adapted to be responsive to arterial pulsation for providing a pulse signal, pressure applying means for applying controlled pressure through means including said pressure sensitive transducing means to the patient skin and maintaining said controlled pressure within the range of substantially just above the diastolic pressure of said patient and a pressure substantially half of said diastolic pressure, and means for detecting the change in said pulse signal during and after a heart straining maneuver relative to said pulse signal just before said heart straining maneuver.

A method of evaluating the mechanical condition of a heart, which method includes the steps of: non-invasively providing a pulse signal representative of arterial pulsation by placing pressure sensitive transducing means for providing an electrical signal representative of pressure, in contact with the skin of a patient while applying pressure at least in part through the pressure sensitive transducing means to adjacent skin at a controlled pressure within the range of substantially just above the diastolic pressure of said patient and a pressure of substantially half of said diastolic pressure, subjecting said patient whose blood pressure is characterized by said pulse signal to a heart straining maneuver, and detecting the change in said pulse signal after said maneuver relative to said pulse signal during a base period before said maneuver.

The Re Application for Patent of Goldenberg, 22 C.P.R. (3d) 159 decision, referred to by Mr. Mitchell in both his written and oral arguments, clearly finds that diagnostic techniques are patentable. In their decision, the Patent Appeal Board said, in part:

... patents for medical treatment in the strict sense must be excluded under the Patent Act. In determining whether or not the applicant's method is a diagnostic method and therefore patentable, we are unable to find, in reviewing the claims as they pertain to a non-medical treatment, using pharmacologically inert substances within the context of the application, that they are directed to more than a diagnostic treatment.

The Webster's Third New International Dictionary defines "diagnostic" as meaning adapted to or used in diagnosis, and "diagnosis" as the art or act of identifying a disease from its signs and symptoms. The invention, as disclosed in the application, is a method and an apparatus for detecting abnormal heart function by recording the change in the amplitude and rate of arterial pulsations after the patient performs a heart straining maneuver, such as expiring forcibly into a confined space for a predetermined interval. The data thus collected allows a skilled practitioner to evaluate the patient's heart function and detect an abnormal heart condition. It is the view of the Board that this application discloses an invention that is purely diagnostic and in deciding on the two objections raised by the examiner we have kept in mind the diagnostic nature of the claimed subject matter.

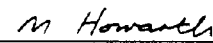
Diagnostic devices and methods, by their very nature, require the presence of a human subject. Claims are patentable which define the structure of the apparatus and the method of diagnosis, provided that such use does not constitute medical treatment. The heart straining maneuver referred to by the examiner may constitute a voluntary effort on the part of the patient being diagnosed, but there is no therapeutic benefit derived from this maneuver, nor does the act of expiring require any special skill or training. We find that the apparatus is not dependent on this maneuver, and that the means for detecting the change in the arterial pulsations is through the pressure sensitive transducing means claimed in Claim 1. The apparatus and method will produce the claimed results when used by a normally skilled practitioner in the assessment of various patients, provided that the patients are capable of breathing. Thus, we feel that the mention of the heart straining maneuver in the claims does not render them indefinite.

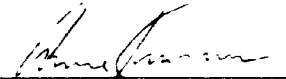
Similarly, we also reverse the rejection on lack of commercial value. If diagnostic methods are to be patentable then commercial

value can not be assessed as if they are processes for producing milled feedstock. The test must be that the method, and its result, has value to the community to which it is addressed; that the method be reproducible by anyone skilled in the art; and that some economic benefit can be realised by those who practice the method. We see no reason to doubt that the method claimed in this application will not be useful to the medical community. Likewise, we believe that the diagnosis would be reproducible for any given patient and would not be dependent on the operator's judgement, but on the condition of the patient's heart. The method can be worked on a commercial scale that is adequate and reasonable under the circumstances, and which will certainly result in some form of economic benefit for the practitioner.

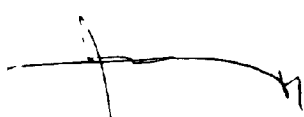
In summary, we believe that the rejected claims clearly define the invention of the applicant in accordance with Section 34(2) of the Patent Act, and that the method claimed has a commercial value as expected for a diagnostic procedure. Therefore, we recommend that the refusal of the claims be withdrawn.


F.H. Adams
Chair
Patent Appeal Board


M. Howarth
Member
Patent Appeal Board


A. Kinsman
Member
Patent Appeal Board

I concur with the findings and the recommendation of the Board. Accordingly I remand the application to the examiner for prosecution consistent with the findings of the Board.


J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec
this 7th day of February 1992

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