Commissioner's Decision

Subject Matter, Sec. 2: Detection of Pathogens

A continous small amount of blood from an individual flows through an exterior absorbent device and returned to the individual. Biocompatible material in the device attract the pathogens after removal of the device its contents are tested in vitro. Method claims are acceptable.

Rejection: Withdrawn

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 319,105 (Class 150-11) filed January 4, 1979. It is assigned to Boehringer Mannheim G.m.b.H., and is entitled PROCESS AND DEVICE FOR THE DETECTION OF PATHOGENS. The inventors are F. Keller and H. Henneman. The Examiner in charge issued a Final Action on November 26, 1982 refusing to allow the application. During a telephone conversation on December 31, 1986 with Applicant's Patent Agent, Mr. Kevin Murphy, agreement to a review of the subject matter under rejection was reached, and the request for an oral hearing withdrawn.

The application describes a method and apparatus for the detection of pathogens in blood. A continuous small amount of blood from a person is caused to flow in the presence of an anticoagulant agent through an exterior adsorbent device, and to return to the person. The device contains a biocompatible material to permit binding thereto of any pathogens in the blood. The device is removed and its contents tested in vitro. The sole drawing, reproduced below, depicts the system. The blood flows exteriorly via tube 14 through adsorbent material 5 in device 2 to tube 15. End caps 8 and 9 permit easy removable of the device.

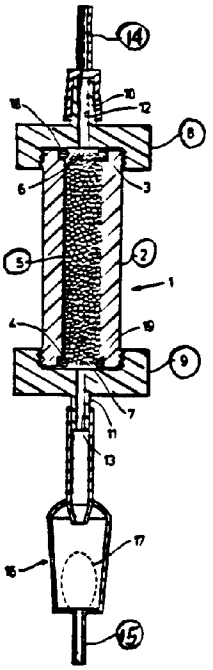

FIG.1.

The Examiner rejected the claims directed to the method. He reasoned that by incorporating the extracorporeal circulation of the blood flow from the human body into a diagnostic procedure, the human body plays an integral part in the process. He indicated the claims to the device are allowable.

In his response to the Final Action, the Applicant points out that the essential steps of the invention occur externally of the body, and that there is no recitation of a human body in the method claims. He argues, in part, as follows:

> It is not seen why the claimed method should be considered any different from other diagnostic methods carried out in vitro. In other diagnostic methods a sample of body fluids such as blood or urine is taken from the body, by, for example, a blood lancet, and the test is conducted on the fluid and the fluid is then disposed of. In the present case the fluid, i.e., blood, is taken from the body, but instead of "disposing" of the fluid after the testing, it is returned to the body, however, this is not at all essential to the character of the diagnostic process which is essentially an in vitro process and certainly the selective binding of the pathogen to separate it from the blood, and the detection step itself are conducted in vitro outside the body.
>
> ...
>
> It is immaterial whether the activity or process carried out on the fluid is carried out discontinuously or continuously, and it is immaterial whether the fluid is subsequently returned to the body. What is notable in the claimed process is that the essential steps of the invention, namely the removal of the pathogen from the blood and the detection step, take place neither within the body nor on the surface of the body, but completely externally and remote from the body.

The issue before the Board is whether or not the process claims 1 to 32, and 54 to 62, are patentable within the definition of Section 2 of the Patent Act. Claim 1 reads:

> A process for the detection of pathogens in blood in the presence of an anticoagulant agent, wherein the pathogen is separated from the blood in an extracorporeal circulation of the blood with a biocompatible material effective to selectively bind the pathogen, whereafter the pathogen is detected in vitro.

In the application we note a feature of the Applicant's method is that a small amount from the person's total blood volume is circulated externally

of the body, and that the amount is continuously withdrawn and returned. The Applicant identifies deficiencies in previous systems for diagnostic detection of pathogens, the main ones being an intermittent flow of fluid, and the inclusion of antibiotics in the blood of people being tested for pathogens. In Applicant's response of September 30, 1981, he discusses the importance of the small volume, as follows:

> ... the small volume of the column is a not insignificant feature of the device of the present invention since the small volume prevents a drop in blood pressure, thrombocytopaenia, loss of immune globulins, adsorption of administered medicaments and at the same time haemolysis is substantially minimized.

Applicant stresses that his method of using continual flow of blood provides an opportunity to obtain samples of pathogens that are randomly distributed throughout a person's body, whereas in intermittent samples pathogens may not be present, or may be obscured due to the presence of antibiotics. He points out that his method returns the blood to the body after it passes through his sampling device, whereas intermittent samples are not. Applicant notes his process of extended continual sampling enables a large part of the total volume to be sampled. He relates that his sampling device is taken out of the line of continual flow and tested elsewhere in vitro.

We are persuaded that in the present arrangement the step of externally adsorbing certain elements does not amount to a treatment of a person's blood, nor to a treatment of a human body, since no steps of treating the blood are introduced, and the blood is merely returned to the body. We note for example, that when a patient, because of renal failure, is treated by haemodialysis, Applicant's arrangement is designed to be connected into the arterial link of the tube system of the dialysis machine after the blood pump.

No substance is added by Applicant's method to the blood returning to the body. That blood is recirculated along with the blood present in the body, and any pathogens present in the body are caught up in the flow. Continuous withdrawal of blood thus provides an extended sampling for pathogens by the adsorbent device which is designed to remove them.

In the Swift & Co.'s Application (New Zealand) (1961) R.P.C. 147, there was considerable discussion concerning whether or not a method of injecting an enzyme into an animal's body prior to slaughtering the animal, to enable circulation of the enzyme through the animal's circulatory system for purposes of tenderizing the meat by the action of the enzyme, was a manner of manufacture. The Court looked to the ultimate end result of the process, namely the production for commercial purposes of a carcass having tenderized meat. The Court noted there might have been an affect on the animal's metabolism, but did not consider the process to be equivalent to a medical process.

Here, Applicant is using a person's circulatory system to emit a continual small flow of blood and to take back substantially that same quantity of flow. Nothing is added to the blood, although certain elements therein may be removed. If we look to the end use of Applicant's process for the detection of pathogens in blood, we see no treatment of the blood is contemplated nor effected. Moreover, no curing or alteration of the metabolism of the body is obtained.

In our view, the arrangement described by Applicant pertains to a diagnostic method and not to a method of medical treatment. We are satisfied therefore, the method set forth in the application is directed to patentable subject matter. Accordingly, we are unable to sustain the rejection by the Examiner on the basis that the incorporation of the function of the human body renders claims 1 to 32, and 54 to 62 unpatentable.

We are not so sure however, that the rejected method claims incorporate all the steps that are described in the application, and that have been argued by the Applicant in his responses, as forming the method of the invention. For example, the claims do not describe that a limited quantity of blood with respect to the total volume in the body is externally circulated in the presence of an anticoagulant in an extracorporeal line and returned to

the body, nor that the extracorporeal line has removably connected therein a device containing an adsorbent biocompatible material so that the device may be removed for diagnostic detection in vitro for pathogens that may have adhered to such material.

We recommend that the rejection of method claims 1 to 32, and 54 to 62 for being directed to non patentable subject matter, be withdrawn, and that the application be returned to the Examiner for normal further prosecution.

M.G. Brown
Acting Chairman
Patent Appeal Board

S.D. Kot
Member

I concur with the findings and the recommendation of the Patent Appeal Board. Accordingly I withdraw the rejection of claims 1 to 32, and 54 to 62, and I remand the application to the Examiner for normal continued prosecution.

J.H.A. Gariépy
Commissioner of Patents
dated at Hull, Quebec
this 26th day of August, 1987

Swabey, Mitchell, Houle, Marcoux & Sher
111 Richmond Street West
Suite 200
Toronto, Ontario
M5H 2G4