PATENTS ACT 1977

IN THE MATTER OF patent application
No. 82-21174 in the name of Jorg Schultz
and partner

STATEMENT OF REASONS

At a hearing held on 4 November 1986 the applicants were represented by their agent Mr Corfield of A R Davies & Co, and Mr C J Luck attended as examiner. On that day I gave an oral decision in which I held that claims 1-4 and 10 as filed on 13 March 1986 are not allowable under the provisions of Sections 1(1)(c) and 4(2) of the Act. I indicated that I would give my reasons for that decision in writing after the hearing. The relevant facts and reasons are as follows:-

Claim 1 reads:-

> Method for the purification of blood by elimination of, in particular, urinary substances through a semi-permeable membrane, according to which non-purified blood in the circulation is conducted along one side of the membrane and dialysis fluid in a closed filtrate circuit is conducted along the other side of the membrane and is regenerated, whereby excess dialysate is removed, characterised in that the method is commenced with a rapid, pure ultra-filtration until the filtrate circuit is filled without foreign dialysate and that thereafter only the filtrate in the filtrate circuit is used as dialysis fluid.

Claims 2-4 relate to preferred features of this method and claim 10 is an omnibus claim to such a method in the usual form.

Claim 5 is an apparatus claim and reads:-

An artificial kidney for the carrying out of the method according to any of claims 1 to 4, with a first conducting system for the production of an extra-corporal bloodstream a haemofilter with a semi-permeable membrane connected to the first conducting system, the blood being conducted along one side of this membrane, and a second conducting system in the form of a closed circuit along the other side of the membrane with a filtrate pump, a branching point, from which a tube branches off to carry away the filtrate, and downstream from the branching point an adsorption system arranged for the regenerating of the filtrate, the filtrate pump being arranged upstream from the branching point, and the filtrate removal tube and in the closed circuit downstream from the adsorption system each has a manually regulated shut-off valve or metering valve and the closed circuit has a flowmeter downstream of the branching point.

In carrying out the method of claims 1-4 and 10 the preferred embodiment involves connecting up the artificial kidney of claim 5 to the human body. All embodiments disclosed involve the egress of blood from the body and the return of blood to the body in a continuous closed circuit. There is no disclosure of the treatment of blood in which, after removal from the human body, it is at some later point in time treated in an apparatus such as the artificial kidney. Mr Corfield did however suggest that this could be done. The apparatus is indeed separate from the human body but it is connected thereto so that at all times the blood remains in a closed circuit of which the human blood vessels form part.

The examiner objected to claims 1-4 and 10 as being unallowable in view of the provisions of Sections 1(1)(c) and 4(2) which read as follows:-

Section 1(1) - A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

(a) .....

(b) .....

(c) it is capable of industrial application;

(d) .....

and references in this Act to a patentable invention shall be construed accordingly.

Section 4(2) - An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

Mr Corfield based much of his argument on the fact that he regarded treatment of blood outside the human body as not being, in the words of Section 4(2), a treatment by therapy "practised on the human ..... body" (my emphasis). Whilst, as indicated at the hearing I do not accept that argument, I do not think that that argument helps Mr Corfield since I do not regard the words "practised on the human ..... body" as qualifying treatment by therapy. In my view they only qualify the word "diagnosis". Thus to fall foul of the therapy limb of section 4(2) the method concerned need merely be "a method of treatment of the human ..... body by ..... therapy." In the present application the apparatus concerned is connected up to the human body and therefore I regard the method as treatment of the human body. The only question that remains open is whether it can be regarded as involving therapy.

On the question of therapy Mr Corfield argued that since by

dialysis and filtration of blood in the method of the invention one is not curing anything, because the condition being treated is incurable, then it cannot be therapy because in dictionary definitions of therapy there is an implication of curing or curative procedures. So far as the meaning of therapy in Section 4(2) is concerned this has been made clear by Falconer J. in Unilever Ltd's Application 1983 RPC 219 at p.230 lines 5-8 where he said:-

> 'In my judgment the word "therapy" in Section 4(2) is to be construed in its wide meaning as including preventive, that is to say, prophylactic, treatment as well as curative treatment of disease of the human body and the animal body.'

Thus therapy must be construed in a wide sense and in my view includes the method, the subject of the present invention, which is directed towards alleviating at least temporarily the symptoms of a particular disease eg. kidney disease rather than curing it. I would cite as other examples of treatment which only alleviate symptoms - (i) the administration of painkillers and (ii) the administration of insulin, which contains the symptoms of diabetes mellitus without curing it.

My attention was drawn to the decision in Calmic Engineering Co Ltd's Application 1973 RPC 684. In that case Graham J decided that a method almost identical to that of the present invention, so far as the matters at issue in the present case are concerned, was not patentable. Mr Corfield argued that that case was decided under the old act where the test of patentability was whether the invention was a manner of new manufacture. For the reasons given above I do not think that the law has changed in this matter and that therefore Calmic remains good law so far as the patentability of this type of process is concerned.

Mr Corfield also referred me to the Guidelines for examination in the European Patent Office (EPO) CIV 4.3 which reads as follows:-

> Treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability.

He relied on the fact that the blood is removed from the body in his method. However in view of the remaining passage in the same guideline which reads:-

> 'in so far as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded.'

I do not think this really helps his argument. He also drew my attention to an unspecified German application where a similar process was allowed. I would simply say that I can only apply United Kingdom Law and that practice in the German Patent Office can be of little relevance. As will be seen from the above quotation from the EPO guidelines, German practice has not been adopted by that office.

For these reasons I refused claims 1-4 and 10 as filed on 13 March 1986, as being not allowable under the provisions of Sections 1(1)(c) and 4(2) of the Act.

Dated this TWENTYFIFTH day of NOVEMBER. 1986

[redacted]

N J MILES
Principal Examiner, acting for the Comptroller.

THE PATENT OFFICE