COMMISSIONER'S DECISION

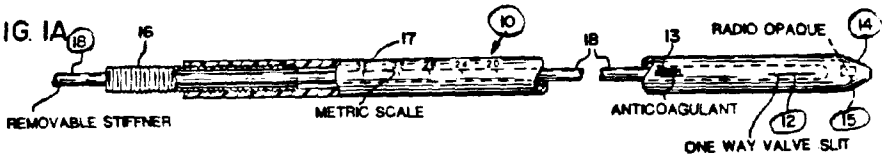
S2 Medical Treatment: Intravenous Therapy and Hyperalimentation

The steps of inserting a catheter into a body and determining its placement in a living body i.e. in the domain of the professional skills of a medical practioner performing a medical or surgical method. Rejection of claims to non patentable subject matter affirmed.

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 394,006 (Class 128-91) filed January 12, 1982, assigned to Catheter Technology Corporation entitled Methods and Apparatus for Intravenous Therapy and Hyperalimentation. The inventors are Leroy E. Groshong and Ronald J. Brawn (Deceased). The Examiner in charge issued a Final Action on September 17, 1984, refusing to allow the application. A Hearing was held on October 2, 1985, at which Applicant was represented by his Patent Agent, Mr. Michael D. Manson.

The application relates to methods and apparatus for short term and long term intravenous, IV, therapy including hyper-alimentation. Figures 1A and 2B reproduced below, show the catheter used for feeding the IV fluid.

FIG. 1A



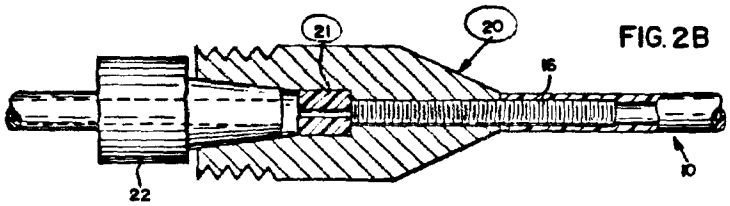


FIG. 2B

In the illustrations reproduced below, the manner of inserting the catheter into a patient for short term therapy is shown by figures 5A and 5C, and the manner of subcutaneously positioning the distal end of the catheter for long term therapy is depicted by figures 6D and 6F.

FIG. 5A

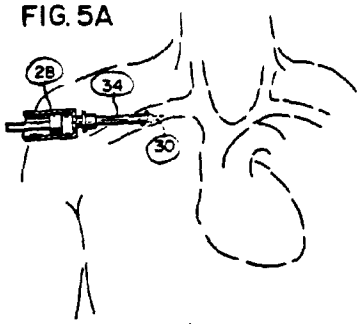


FIG 6D

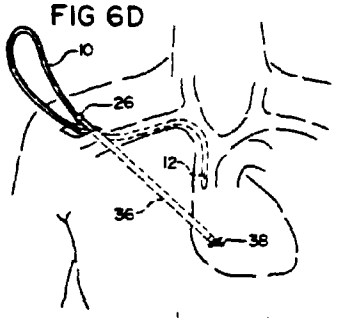


FIG. 5C

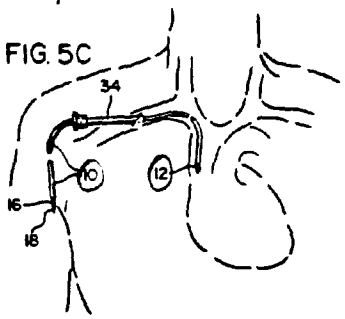
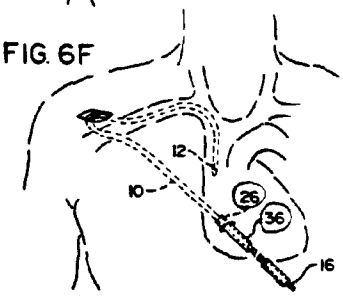


FIG. 6F



The proximal end 14 of catheter 10 (figure 1A) has a one way valve 12 adjacent to it and has a radio-opaque substance 15 therein. In use the one way valve permits fluid to flow only from the inside of catheter 10 to the outside due to pressure of the IV fluid. The removable stiffener 18 is used to position the catheter inside the vein, and the substance 15 permits detection by x-ray during positioning. The flow reducer 21 regulates the IV fluid.

To position the catheter (fig. 5A) a syringe 28 with a needle 30 is used, having a shield 34 placed over the needle. After penetrating the vein the syringe is used to withdraw a quantity of blood sufficient to ensure

proper entry. The sleeve is moved forwardly, held, and the needle and syringe removed. The catheter, filled with IV solution to eliminate air from its interior, is inserted through the sleeve into the vein, and its proximal end moved by the stiffener to its limit as determined by means of the radio-opaque material and x-ray (figure 5C). The sleeve is then removed over the distal end projecting from the patient and the catheter secured at the incision. Flow reducing adapter 20 (figure 2B) with restrictor 21 is then positioned on the distal end.

For long term IV therapy (fig. 6D), the shoulder area and catheter exit area e.g. the chest, are prepared for surgical incision, including local anaesthetic. The passer 36 is inserted to provide for passage of the catheter to the exit point, followed by securing the catheter, removing the passer, closing the incisions, and coupling an IV source to the distal end.

In his Final Action, the Examiner refuses all the method claims, 1 to 28, for being directed to non-statutory subject matter and therefore "...outside the definition of invention given in Section 2 of the Patent Act." He indicates claims 29 to 32 are allowable. His rejection of the method claims reads:

> Claims 1 to 25 and 27-28 are directed to a method of treating humans by means of therapy and claim 26 is directed to a surgical method. These claims also include steps usually performed by a medical practitioner in the normal practice of his profession.

The Applicant however, believes the Examiner is not applying Tennessee Eastman v The Commissioner of Patents (1974) SCR 111 against the factual situation of this application. The applicant argues, as follows, in part:

> ...there is nothing in Section 2 in respect of the definition of "invention" which provides grounds for rejecting an application for patent of a method for such therapy. The definition of "invention" in Section 2

> includes any new and useful process. The claimed method is clearly a new and useful process. The utility of such a process is clearly disclosed in the application. The applicant submits that the subject matter claimed in claims 1 to 28 of this application is patentable subject matter within the definition of invention as given in Section 2 of the Patent Act.

The Applicant comments that he is entitled to the grant of a patent unless the Commissioner can determine by law that no patent should be granted, and he draws attention to Monsanto v The Commissioner of Patents (1979) 42 C.P.R. (2d) 161 at 178 and the words of Mr. Justice Martland as follows:

> 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 therefore.
>
> 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 The Commissioner of Patents, (1938) 4 D.L.R. 657, (1939) S.C.R. 245 at page 246:
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> > 'No doubt the Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation'.

The issue before the Board is whether or not the subject matter of claims 1 to 28 is patentable under Section 2 of the Patent Act. Claim 1 reads:

> A method of performing intravenous therapy including hyperalimentation comprising the steps: inserting the proximal end of a flexible catheter having a one way valve adjacent its proximal end through the skin of a patient and into a vein having a suitably large flow of blood therethrough; coupling the distal end of the catheter to an interchangeable static flow reducing means capable of restricting flow of fluid, from a source positioned to provide a predetermined fluid head, into said catheter at a rate no greater than a predetermined clinically described flow rate, coupling a source of intravenous solution to said flow reducing means, positioning said source at an elevation to provide said fluid head, and allowing said solution to flow by gravity through said flow reducing means into said catheter and thence into said vein.

At the Hearing, the importance of the words 'by law" found in Monsanto supra, was stressed by Mr. Manson in making the following observations: Section 2 does not preclude a method of medical treatment but refers to "any new and useful art", there is nothing in the jurisprudence to limit the kinds of method that the Applicant claims, and part 12.03.01(b) of the Manual of Patent Office Procedures has no foundation in law or statutorily and provides no basis for the Patent Office to limit the scope of Section 2. He reasons therefore, Applicant's method with its specialised instructions of insertion of a catheter to provide food to an animal body should be allowed. In Mr. Manson's view, the method claims contain only mechanical steps to provide nutrition and the step of inserting the catheter is an incidental step. He argues the steps represent the "means" to attain an "end", and are not claiming the "end". He further reasons that even if the Board is inclined to find the scope of Section 2 can be limited, noting that the Applicant does not agree with such a view, the methods of the Applicant's claims relate to performing intravenous (IV) therapy which include alimentation or total parenteral nutrition to an animal body including humans. Mr. Manson asserts they are not directed to medical treatment. He contends the steps are for insertion, with specialized instruction, of a catheter into a large vein in the body to provide nutrition. He points out the Applicant's claimed methods are not related to diagnosis, prevention, or curing of an ailment. He says the Applicant is willing to limit the scope of the claims by deleting from the first lines of claims 1, 2 and 15 the words "...performing intravenous therapy including...", leaving only a method of hyperalimentation i.e. total parenteral nutrition, that in his opinion would clearly be outside the scope of a medical treatment. He argues the fact of inserting a needle, a catheter, or a device into a human body is only incidental.

Mr. Manson discusses a passage from Tennessee Eastman supra p.118, arguing it is directed to the use of a substance that would affect the organic workings of a human body; the passage reads:

> "It is clear that a new substance that is useful in the medical or surgical treatment of humans or of animals is an 'invention'. It is equally clear that a process for making such a substance also is an 'invention'. In fact, the substance can be claimed as an invention only 'when prepared or produced by' such a process. But what of the method of medical or surgical treatment using the new substance? Can it too be claimed as an invention? In order to establish the utility of the substance this has to be defined to a certain extent. In the case of a drug, the desirable effects must be ascertained as well as the undesirable side effects. The proper doses have to be found as well as methods of administration and any counter-indications. May these therapeutic data be claimed in themselves as a separate invention consisting in a method of treatment embodying the use of the new drug? I do not think so, and it appears to me that s.41 definitely indicates that it is not so.
>
> Section 41 was enacted for the purpose of restricting the scope of patents "relating to substances prepared or produced by chemical processes and intended for food or medicine'. The first principle proclaimed is that in the case of such inventions, 'the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described in the claim or by their obvious equivalents'. In my view, this necessarily implies that, with respect to such substances, the therapeutic use cannot be claimed by a process claim apart from the substance itself. Otherwise, it would mean that while the substance could not be claimed except when prepared by the patented process, the use however prepared could be claimed as a method of treatment. In other words, if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s.41(1)."
> (emphasis mine)

Mr. Manson regards this statement as an expression of Mr. Justice Pigeon's concern over the attempt, by trying to patent a method of medical treatment in relation to a substance, to skirt around Section 41, and of the concern that, by claiming a method of medical treatment and by not having process or product by process claims, it would be possible to avoid the import of Section 41. Mr. Manson believes the statement is restricted to the fact situation there, and has no relevance to Applicant's apparatus and method claims.

Mr. Manson points to page 120 in Tennessee Eastman supra, where Mr. Justice Pigeon commented that cases in Britain, Australia and New Zealand dealing with the patentability of medical treatment should not be given the weight that certain authors feel they should be accorded. Mr. Manson emphasizes the Applicant's method is to the use of an apparatus and is directed to any medical practitioner including nurses concerned with IV feeding. He believes the findings by the Patent Appeal Board in re Application 880,719 (Patent No. 944,693) 18 C.P.R. (2d) 114 support his contention, noting the Board there found the "means" distinct from the "end". The subject matter relates to the use of fluorescent dyes for a dental application. The Board considered the process used therein did not apply any pharmaceutical properties to affect a curative or preventive treatment, and that there was no step of medical or surgical treatment in the claims. The Board also referred therein to a passage quoted by Mr. Justice Pigeon in Tennessee Eastman page 121 from in Re Schering A.G.'s Application (1971) R.P.C. 337, at 345, and we note here the emphasized portion as follows:

> ...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,...

In commenting on the description of the short term and long term therapy Mr. Manson considers there is nothing in the steps of Applicant's claims to suggest surgical or medical treatment, emphasizing there are only

mechanical steps of inserting the catheter and making connections for IV feeding. He acknowledges a certain threshold level of skill by a person skilled in the art to place the catheter in the vein, but stresses that Applicant's method is not the equivalent of a medical operation in the true sense that it is trying to correct an ailment or prevent something from spreading or to remove some part of the body.

Concerning Mr. Justice Pigeon's reference with respect to the emphasized portion from in Re Schering, Mr. Manson believes Mr. Pigeon regarded that phrase in the same way he expressed himself on page 119 of Tennessee Eastman, supra, "...having come to the conclusion that methods of medical treatment are not contemplated...the same must...be true of a surgical treatment...". Mr. Manson links these comments to the concern by Mr. Justice Pigeon in preventing an applicant from skirting Section 41. After noting the reference in Schering was obiter dicta, Mr. Manson returned to Applicant's proposal to limit the wording of claims 1, 2 and 15, saying the claims then would be restricted to the feeding aspect of the application.

Mr. Manson's attention was directed to claim 15 and the various steps of; incising a patient's skin, dissecting tissue to reveal a vein and incising the vein, feeding the catheter to the desired position, threading a passer tube subcutaneously to an incised exit area and passing the catheter therethrough, and closing the incisions. Observing there is a higher level of skill here, Mr. Manson however feels these are only mechanical steps performed by the person in the art, i.e. the medical art.

Responding to an observation that Applicant's claims could be considered as teaching the medical profession how to do its tasks, Mr. Manson argues the steps are directed to technicians in the art area and relate only to mechanical procedures which incidentally are in the medical field.

Responding to questions on the method set forth in claim 26, Mr. Manson indicates a willingness to delete the claim, but not the other claims wherein the steps are performed the same way each time. Mr. Manson differentiates the others from the subject matter in Lawson vs. The Commissioner of Patents (1970) 62 C.P.R. p. 109. In Lawson, he feels the design could not be reproduced the same way each time, and that the skills of the designer control the process.

Concerning the operation involving the incision in a patient to insert a catheter, Mr. Manson dealt with the term "operation" as having different degrees of interpretation, saying, in terms of medical or surgical treatment, it is done within the context of removing, curing, or treating, to achieve an end result by medically treating the body. He believes that Applicant's operation of inserting the catheter through the skin into a vein has nothing to do with the end result of treatment, saying it is merely a mechanical way in which the apparatus is placed to apply nutrition through the device into a body: in his view not a medical treatment.

We deal first with Lawson supra. We regard the direction given by the decision differently from Mr. Manson. In our opinion the Court considered it settled that all new and useful arts and manufactures do not reside within the definition of invention. In Lawson, Cattenach J. pointed to a passage from Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning vs. The Commissioner of Patents (1962) 39 C.P.R. 105 at 124 in which Thorson P. said if an art or manufacture were:

> ...new and useful it is an invention within the meaning of the definition and, therefore, patentable under the Act...

Cattenach J. then referred to the appeal from Thorson's decision as follows:

> On appeal the view of Thorson, P., as above expressed was repudiated by the Supreme Court of Canada...

and concluded:

> It is, therefore, clear that words of limitation must be read into s. 2(d).

In Cattenach's opinion, the procedure of dividing land did not reside in a patentable art area in Canada, notwithstanding that in the United States Patent Office the Board of Appeal found certain claims acceptable.

In determining the kind of subject matter presented by Applicant, we find direction in The Commissioner of Patents vs Farbwerke Hoescht Aktiengesellschaft Vormals Meister Lucius & Bruning (1964) S.C.R. at 55 where Judson, J. said:

> Following statements made in R. v Patents Appeal Tribunal, Ex p. Swift & Co., the Exchequer Court said that the Commissioner should not refuse to allow an application to proceed to the grant of a patent unless he is quite satisfied that the subject-matter of the application could not conceivably be patented within the meaning of the Patent Act.
>
> The Commissioner was well within even this definition of the scope of his duties but I think that the obiter of the Exchequer Court expresses the duties of the Commissioner too restrictively and fails to recognize the distinction between the United Kingdom and the Canadian Patent Acts. Under ss 6, 7 and 8 of the United Kingdom Patents Act 1949, the Examiner may examine only for anticipation. He may not and does not as a matter of practice examine as to inventiveness. This is left to the Court. Further, as pointed out in Re Levy & West's Application, no appeal lies from the Patent Appeal Tribunal, whereas in a subsequent action the validity of the patent may be impeached in the highest court in the land.
>
> In contrast, in Canada the Patent Office, supervised by the Court, does examine as to inventiveness, and an applicant may appeal to the highest court. Moreover, in the particular class of case with which we are here concerned dealing with drugs and medicines, there is considerable public interest at stake, and the Commissioner should most carefully scrutinize the application to see if it merits the grant of monopoly privileges and to determine the scope of the monopoly available.

In the above passage, Judson J. points out that applications are examined to determine the presence of inventiveness, and he stresses that it is the Commissioner's duty to determine the patentability of subject matter, particularly where there is a perceived public interest in the application.

We look now to the significance of the whole passage from re Schering page 345, which Pigeon, J. referred to just prior to dismissing the appeal in Tennessee Eastman:

> 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) 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)

Mr. Manson viewed the emphasized portion in Schering as being an obiter comment by Mr. Justice Pigeon rather than a statement relating to the facts. We do not fully share that view. We consider the emphasis placed on the statement is in accord with Mr. Justice Pigeon's conclusion on page 119 that methods of medical treatment are not contemplated under Section 2. Moreover there are other points in Schering which we believe relate to the issue before us. One is that the Appeal tribunal considered that patents under the Patents Act in Great Britain "...for medical treatment in the strict sense must be excluded...". Another is that neither the Appeal Tribunal nor the United Kingdom Patent Office were deciding "actual patentability"; it is said the High Court decides such matters. Comparing these comments in Schering to the direction laid down by Mr. Justice Judson ((1964) S.C.R.), we find one of the Commissioner's duties is to scrutinize an application and determine if it merits a patent grant. When the subject matter relates to medical treatment, we believe Mr. Justice Pigeon, by emphasizing the portion from re Schering, provides direction that medical treatment is not patentable.

Moreover, we are persuaded Mr. Pigeon's reference to the emphasized portion is more than obiter dicta, particularly since it was not emphasized on page 345 in the manner given to it by Mr. Justice Pigeon.

We see nowhere in the remarks made by Pigeon, J. in Tennessee Eastman supra, that the findings by the Exchequer Court, 8 C.P.R. (2d) 202, when the case was before it, should be disregarded, and we refer to the reasoning provided by Kerr, J. in the following passage:

> The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field. Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject matter for patents, as indicated by authoritative judgements that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of s. 2(d) of the Patent Act.
>
> (our emphasis)

Even assuming that Applicant's method could be administered by someone other than a physician, it is our opinion that from the direction given by Kerr, J., a method which lies in the professional field of medical treatment is not patentable under Section 2.

In Schlumberger Canada Ltd. v The Commissioner of Patents (1981) 56 C.P.R. 204, Section 2 of the Act was reviewed in dealing with a computer program, and Pratte J. said:

> As to mental operations and processes it is clear in my view that they are not the kind of processes that are referred to in the definition of invention in s. 2.

The preceding cases before the Canadian Courts have directed that the wording in Section 2 must be given restrictive meanings. They also provide authoritative judgements, and in view of them, we believe sufficient reasons, by law, are provided to meet the requirements of Monsanto, supra, which Mr. Manson relies on.

In each of the rejected claims the first step involves insertion of an instrument through the skin and into and within a selected vein. In the description of the kinds of IV therapy, our attention is directed to the role of the physician who in each type of therapy selects the vein e.g. cephalic, subclavian, internal jugular, external jugular, basilic, or median cubital. Local anaesthetic is injected around the area of insertion and the area surgically prepared. Our attention is drawn in the first example to the importance of the syringe and needle to ensure no air is entrapped in the fluid flow, and to the sleeve surrounding the needle to provide a passage for the catheter to the vein. Again in the second example, the syringe is highly significant as it is used to aspirate air to prevent an air embolism when a catheter is placed in a vein without filling the catheter with the IV fluid. In our view the description of these procedures alone represents steps carried out in a medical treatment. Moreover, the skill in determining the progress of the catheter travel inside a vein to a desired location, for example in the superior vena cava, using the radio opaque material and the x-ray equipment, readily persuade us that a level of professional skill is involved equivalent to that used in medical and surgical treatments. We are further persuaded to this view when consideration is given to the many different individuals presenting different health and physical conditions that have to be assessed before and during the catheter placement.

To accept Applicant's view that only mechanical steps are involved, we would have to consider for example, in achieving fluid flow from one point to another, that passing a catheter by means of a stiffener through a vein is equivalent to passing a hose through a conduit under a street; a comparison that is untenable in our view. We are informed too that a passer tube must be threaded subcutaneously through the body of a person, and the incisions

finally closed. We find the levels of skill involved in Applicant's methods lie in the domain of the professional skills of a medical practitioner performing medical or surgical steps in the treatment of a human body. It may well be that certain of the steps in some of the rejected claims may per se be considered mechanical steps, particularly to medical practitioners, however, on consideration of the overall subject matter we are satisfied that the requisite level of skill to perform Applicant's kind of IV therapy relies on expertise found in the field of medical treatment. We find claims 1 to 28 not to be patentable. The claims do contain steps of medical treatment concerning the incision of a body, insertion of a catheter, and clinical treatment of a body including alimentation, whereas in re Application 880,719 no step of medical treatment was found.

The decisions in the cases we have considered in reviewing Applicant's subject matter demonstrate significant developments in the definition of a patentable invention according to the Canadian Patent Act, and identify the determinations the Commissioner must make based on the interpretations given by Canadian Courts. Our review has shown differences in Canada in the practical application of the definition of a patentable invention from the way that patentability is determined in the United Kingdom.

In summary we find that Applicant's method claims recite subject matter that lies in the professional field of surgery and medical treatment, and involves the professional skills of a medical practitioner in treating a human body. We find direction in the jurisprudence discussed herein. We are satisfied the subject matter of method claims 1 to 28 of this application is not patentable within the definition of Section 2 of the Patent Act in view of the jurisprudence.

We recommend that claims 1 to 28 be refused for falling outside the definition of invention in Section 2.

M.G. Brown
Acting Chairman
Patent Appeal Board

S.D. Kot
Member

I concur with the findings and recommendations of the Patent Appeal Board. Accordingly, I refuse to grant a patent on this application containing claims 1 to 28. The Applicant has six months within which to appeal my decision under the authority of Section 44 of the Patent Act.

J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec

this 13th day of August 1986

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