COMMISSIONER'S DECISION

Non-Statutory S.2: The method involves the skills of a medical practioner in inserting into a living body a proper amount of material compatible with the body's anatomy. Rejection affirmed.

This decision deals with Applicant's request for review by the Commissioner of Patents of the Final Action on application 329,163 (Class 128-52) filed June 6, 79. It is assigned to RSP Company and is entitled METHOD AND APPARATUS FOR THE HYSTEROSCOPIC NON-SURGICAL STERILIZATION OF FEMALES. The inventor is Robert A. Erb. The Examiner in charge issued a Final Action on October 29, 1982 refusing to allow method claims 18 to 26 of the application. The remaining claims, directed to the apparatus, were indicated to be allowable. A Hearing was held on June 25, 1986, at which Applicant was represented by his Patent Agent Mr. R. Smart.

This application relates to a method and apparatus for the non-surgical, reversible sterilizaton of females. Figures 4A to 4E, shown below, depict the procedures. Telescoping flexible plastic tube portions 30, 31, of the hysteroscope are used in locating the oviduct and positioning the instrument there in sealing contact. Curing elastomer is introduced to fill the oviduct fully and is allowed to set. The plastic tubes are released and moved relatively to one another to disconnect from the cured material and the hysteroscope removed.

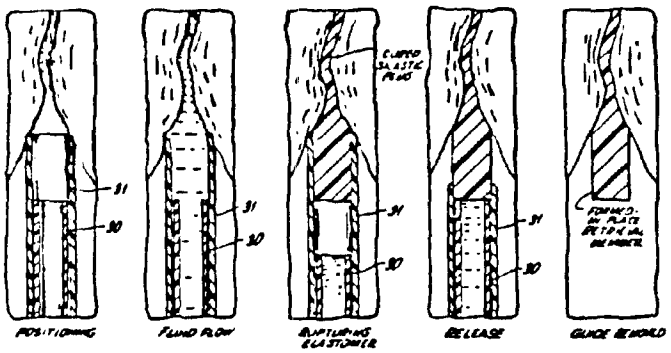

FIG 4A FIG.4B FIG.4C FIG.4D FIG 4E

In rejecting claims 18 to 26, the Examiner said in his Final Action, in part, as follows:

> . . .
>
> The applicant in his letter argues that the method claimed in claims 18 to 26 is patentable because the method in question is directed to a non-surgical method and that a method of birth control is not amongst the examples of non-statutory subject matter set forth in Section 12.03.01(b) of the Manual of Patent Office Practice, i.e., methods of treating humans by surgery or therapy, nor to the diagnosis, prevention or curing of an ailment.
>
> This argument, however, cannot overcome the objection because contraception is a method used to control and prevent discomfort, possible injuries associated with conception or hereditary diseases and therefore it is a method of medical treatment excluded from the definition of patentable invention in Section 2 of the Patent Act.
>
> The applicant also states in his letter that the words "work on a commercial scale" should not be used to test the patentability of a claim and that his method claim 18 is capable of being worked on a commercial scale. Section 67(3) of the Patent Act states that patents should be worked on a commercial scale, and Section 2 of the Patent Act defines "work of a commercial scale" as meaning the carrying on of a process in or by means of a definite and substantial establishment. Also it is an obvious truth to say that a process must result in a vendible product without which the process is not useful.
>
> With regard to applicant's method, it cannot be worked on a commercial scale, such as in factory or similar substantial establishment. Also the method does not result in a vendible product. In fact, the use of the device will be provided as a <u>service</u> for a fee. In the case of applicant's method, there is no starting material which is to be modified by the method to produce a vendible product. The modification which results is a modification of the normal processes of a female human body.
>
> In view of the above points of argument, applicant's method cannot be considered to be a process in the sense intended by the Patent Act and the method is therefore unpatentable. Claims 18 to 26 are required to be deleted.
>
> . . .

The Applicant argues that his method claims are directed to a method of manufacturing an article in-situ, and as such are permissible under Section 2 of the Act. He points to the sequence of steps which obtain the construction of an elastomer material fitted to the particular anatomy of a user. He distinguishes his method claims from those found not to be patentable in <u>Tennessee Eastman v. The Commissioner of Patents</u> (1974) S.C.R. 111.

The Applicant stresses his invention does not relate to a substance intended

> If, as suggested by the examiner, the purpose for which the device made by the claimed process is used, namely to effect birth control by oviduct blockage, is a method of medical treatment, that conclusion does not affect the patentability of the claimed method by which the device is made. At most, it would render the claimed method subject to a compulsory license pursuant to s. 41(4).

To further support his views that the method claims are allowable, the Applicant reasons, in part, as follows:

> There is no requirement in the Canadian Patent Act that requires that a patentable method produce a vendible product. The only requirements are that the method is new and useful, and that it not be obvious.
>
> There is likewise no requirement that a patentable method be capable of working on a commercial scale such as in a factory or similar substantial establishment.
>
> The method of the invention is certainly capable of being worked on a commercial scale in substantial establishments. There is no reason to believe that it could not be worked in birth control clinics, some of which are of substantial size. In some instances, these have been actually referred to as "factories". No one would doubt that their activities are "commercial".
>
> The starting materials for the claimed process are the polymeric material, the catalyst, and in some cases the obturating tip. The claimed method modifies these to make of them the fitted device which is the "vendible" product. It is this product - the device and not the claimed method - which functions to perform the birth control method. That this is so is clear from the fact that the device is non-surgically removable, and that the birth control method cannot be carried out unless the device is left in place in both oviducts throughout at least one menstrual cycle.
>
> None of these assertions of the examiner as to the claimed process have any basis in law as a requirement for a patentable method. None are mentioned as such in the Patent Act. Some of them appear to be lifted from British cases dealing with compliance with the requirements of the British Patents Act, which Act differs markedly from the Canadian Act, as pointed out by Pigeon J. in the Tennessee Eastman case at p. 120.
>
> In sum, it is submitted that the rejection of claims 18-26 by the examiner is not based upon grounds upon which the Commissioner could be satisfied under s. 42 that the applicant is not by law entitled to a patent. (See Monsanto Co. v. Commissioner of Patents (1979), 42 C.P.R. (2d) 161).

The issue before the Board is whether or not claims 18 to 26 are directed to patentable subject matter in view of Section 2 of the Patent Act. Claim 18 reads:

> The method for non-surgically forming in situ a plug to occlude an oviduct comprising the steps of hysteroscopically locating the uterine end of an oviduct; inserting a pair of inner and outer co-extensive telescoping flexible plastic tubes, releasably maintained in fixed relative position one to the other, through the operating channel of the

> hysteroscope and positioning said tubes about the oviduct opening in sealing relationship thereto, the releasing means remaining external of said hysteroscope; dispensing a predetermined amount of curable elastomer-precursor into said oviduct through the inner of said tubes, permitting said elastomer-precursor to cure in situ; releasing said inner and outer tubes one from the other and moving one relative to the other to thereby break the cured elastomer; and withdrawing said hysteroscope tubes.

Mr. Smart argues that Applicant's method is directed to no more than the steps of mechanically blocking an oviduct. He points to page 6 the disclosure of the application where it states that, due to its properties, the elastomeric material will adhere only to other silicone rubbers and not to the body tissues except by flowing into voids to cause mechanical interlocking. He notes the topically external nature of the oviduct, stressing that the elastomer does not cross tissue lines. He describes the flow of the elastomer takes it to both sides of the isthmus neck of the fallopian tube where a mechanical lock forms on curing.

Mr. Smart stresses the non-surgical nature of Applicant's in-situ formation of an elastomer tube to fit the anatomy of the wearer. He notes there is no birth control method recited by the steps. He refers to the retrieving means that is provided on the elastomer plug. He comments that the practice of birth control would occur only if each oviduct had a plug in place for one complete menstrual cycle of the wearer, and that the user would decide this issue, just as the user has the choice of other birth control devices and measures. He reasons that the act of installing the elastomer according to Applicant's method represents a mechanical procedure, and not a birth control procedure, per se.

Mr. Smart looks to the decision in The Commissioner of Patents v. Farbwerke Hoescht Aktiengesellschaft Vormals Meister Lucius & Bruning [1964] S.C.R. 49 at 57, a case dealing with Section 41(1) of the Act, as follows:

> The section was held to be restrictive of the rights that an inventor would have except for the prohibitions of the section. Consequently, the Court should not find that a particular application came within its prohibitions unless the conditions for its application are clearly present. I can see no justification for this interpretation. There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the Patent Act, no more and no less. If the patent for which he is applying comes within the provisions of s. 41(1) of the Act, then he must comply with that section.

his view, this case settled that Canadian patents are creatures of the Patent Act, and that applications should be scrutinized in view thereof.

In referring to Tennessee Eastman v. The Commissioner of Patents [1974] S.C.R. p. 111, Mr. Smart discusses a passage given by Kerr, J. in the Exchequer Court decision in this case, and reproduced in Mr. Justice Pigeon's decision at page 114 as follows:

> In my view the method here does not lay in the field of manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. 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 patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of subsection (d) of section 2 of the Patent Act.

Mr. Smart indicates that Mr. Justice Pigeon makes no comment on this passage. He then refers to certain questions that Mr. Pigeon posed, and observations made in dealing with the matter before him as follows:

on page 117

> ...
>
> The sole question is therefore whether a new use for surgical purposes of a known substance can be claimed as an invention.

on page 118

> ...
>
> Here, we have to deal with a substance that was known and also with its previously known essential properties, that is to form an adhesive by polymerization on application. Therefore, the only element of novelty is in its application to surgical use and the discovery is limited to the unobvious adaptability to such use. This is why the claims, as previously pointed out, are only for a surgical method of joining tissues by means of such an adhesive rather than with thread or clips. Is such a method an "art" or "process" within the meaning of the definition of "invention"?
>
> 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

> 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.

on page 119

> ...
>
> 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, its 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).

Mr. Smart points to the implication given by Pigeon J. that a method of using a medicinal substance is excluded as claimable subject matter. In Mr. Smart's view, Pigeon J. means by a method of medical treatment, simply the application of a medicinal substance. He believes Pigeon J. means the same thing when referring to a surgical treatment. Mr. Smart derives his belief from Mr. Justice Pigeon's conclusion in the passage on page 119, mid-page:

> Having come to the conclusion that methods of medical treatment are not contemplated in the definition of "invention" as a kind of "process", the same must, on the same basis, be true of a method of surgical treatment.

He reasons that Pigeon J. looked on the term medicine as being something that is to be given a wide interpretation on the basis of some earlier cases. Mr. Smart notes that the basis could have been on the fact that surgery is a part of medicine when medicine is being used in its broad sense.

Mr. Smart refers to another passage from Tennessee Eastman, page 121, concerning surgical or medical processes which are excluded, per se. He interprets it as referring to the kind of methods of surgical or medical processes that are related to the application of a medicament to a person, for example, the process of curing a disease by taking a pill, or using an adhesive to adhere pieces of flesh together based on the discovered properties of the adhesive. That passage reads:

> While those decisions may be of some interest in dealing with the patentability of inventions related to slaughtering or agricultural processes, I fail to see anything that would tend to overbear the implication of s. 41(1) with respect to the exclusion of a surgical or medical method per se from the area of patentable process.

In view of the Tennessee Eastman case, Mr. Smart submits that not all methods that produce their effect upon or in conjunction with a human body are methods of surgical or medical treatment in the sense used by Pigeon J.

Mr. Smart discussed the unreported Federal Court of Appeal decision rendered April 21, 1986, Imperial Chemical Industries v. The Commissioner of Patents. There, he reasons, the method claims of applying the substance to the teeth were refused for being a medical process of reducing caries. Mr. Smart refers to the penultimate paragraph of the decision, noting it records that the Commissioner did not err in the basis for refusing the claims, viz, that it was a medical process involving the application of a substance to a human, and that the Federal Court felt itself bound by Tennessee Eastman.

In view of these cases, he believes the implication, based on Mr. Justice Pigeon's ratio, does not extend beyond medical or surgical treatment relying on the use of substances, per se, to effect a treatment due to their properties. Mr. Smart reasons there does not exist an implication, concerning medical processes involving medical or surgical devices, that such processes are unpatentable. He indicates the Act does not contain such an implication.

Mr. Smart submits six Canadian patents 946,084, 968,108, 1,003,167, 1,071,820, 1,150,464, and 1,166,810 having methods of forming casts related to the human body. He says they have a lot in common with the method in the present case, for example, the product being made conforms to the anatomy of the wearer. He suggests in many of these examples, the wearing of the article could be considered a surgical or medical method. He comments however, these methods are not the kind of method which Pigeon J. was addressing in Tennessee Eastman because they are not methods which consist only of the application of a medication or a substance that has physiological properties. He reasons his client's method is worthy of patent protection.

oncerning the Examiner's reference to Section 67(3), Mr. Smart considers that subsection (3) is only for determining abuse of exclusive rights in connection with subsection (2) concerning compulsory licence applications. As such he argues Section 67(3) has no relevance to what is patentable or not.

In summation Mr. Smart relates that claims 18 to 26 are directed to manufacture of a device, and are not directed to a method of surgical or medical treatment, per se. He restates there is nothing in the act to preclude their patentability. Finally, he refers to Monsanto Co. v. The Commissioner of Patents [1979] 42 C.P.R. (2d) 161 at 178, in which the significance of the term, by law, in Section 42 is emphasized. He indicates that reasons found in the Patent Act or in jurisprudence must be presented why his client is not by law entitled to a patent.

As the issue before us relates to the subject matter contained in this application, we make no comments on the claims in the Canadian patents referred to by the Patent Agent. Accordingly, we look to Applicant's subject matter in view of the Patent Act and related jurisprudence.

From the disclosure we see certain methodology is presented in carrying out the method found in claims 18 to 26. On page 11 preparing a patient for hysteroscopic examination is described using standard medical procedures and local anesthesia. A description is given of the type of hysteroscopy fluid that replaces the air in the hysteroscope sheath prior to insertion of the device into the cervical canal. After insertion the hysteroscopy fluid is pressurized to inflate the uterus for a subsequent procedure. This fluid aids in providing visualization of the uterus. An account of identifying the sometimes hard to find tubal ostium is given, including the use of a dye in saline solution. Mention is made of positioning the obturating tip with a force to achieve moderate sealing. Details are given for mixing the ingredients forming the elastomer material to provide the necessary consistency. Proper force to seat the hysteroscope and to propel the elastomer to fill the oviduct and both sides of the isthmus of the fallopian tube, is said to be obtained by simultaneously observing the flow of material during dispensing. After gelling, a retrieval portion is provided by actuating the

apparatus. After the technique is completed for the other tubal ostium, confirmation of plugs of suitable length is determined by a flat x-ray plate.

We look on Applicant's method as essentially involving steps requiring the skills of a medical practioner attending on a patient. We are not persuaded by the arguments advanced by the Patent Agent that the method should be considered as a mechanical procedure in the field of manual or productive arts. It may be that the elastomer is a commercial item and may be patentable, and if so, licenced for financial considerations. We believe however, that the remarks of Kerr J. reproduced in Tennessee Eastman, supra, p. 114, and discussed previously by Mr. Smart appropriately relate to the kind of method in claims 18 to 26 in this application:

> ... but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. 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 mater for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of subsection (d) of section 2 of the Patent Act.

We note that claim 18 is directed to a method pertaining to a living animal body involving, an operating hysteroscope, its insertion and use to pressurize the uterine cavity, its location at the oviduct in sealing relation thereto, dispensing a curable elastomer via an inner portion of the hysteroscope to at least the isthmus of fallopia, permitting curing, and withdrawal of the apparatus to break the cured elastomer near the end of the inner portion. We see this as more than a routine method of forming a product, such as suggested by the Applicant. Mr. Smart acknowledges that probably the operation is performed by an obstetrician. He submits that apart from what Mr. Justice Pigeon found in Section 41(1) there is nothing in the Patent Act saying that processes carried out by doctors or surgeons are any different from a process carried out by anybody else, so far as a patent is concerned. It is true that the Act does not per se, refer to such processes. It is equally true in our view, that the jurisprudence developed by Tennessee Eastman, supra, does deal with medical methods or processes, as is evident from the passage by Kerr J. in interpreting Section 2. Moreover, Mr. Justice Pigeon after inserting the

as previously noted by Mr. Smart, "... that methods of medical treatment are not contemplated in the definition *of* "invention" as a kind of "process", the same must, on the same basis, be true of a method of surgical treatment." We are of the opinion that Mr. Pigeon's remarks cover medical treatment in a broad sense, and not simply the application of a medicinal substance.

At the Hearing, the Board referred to a passage quoted by Mr. Justice Pigeon on page 121 in Tennessee Eastman from in Re Schering A.G.'s Application (1971) R.P.C. 337, at 345, and in particular to 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,...

Mr. Smart suggests it points out the reason the case was allowed in Great Britain. There, he says, they were not examining for patentability, and that by allowing the application any question of patentability could be brought before the Courts. We believe it indicates more. We see the emphasis given by Pigeon J. to the Schering passage is in line with his conclusion on page 119 that methods of medical treatment are not contemplated under Section 2.

We find direction from the Farbwerke Hoescht case discussed by Mr. Smart, in the following remarks made on page 55 by Judson J.:

> 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 Ptent 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 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 our view, Farbwerke Hoescht points out that the Commissioner' duty is to determine the patentably of subject matter and if he finds it is not patentable that he may refuse to allow an application provided he is satisfied by sufficient reasons.

We see the remarks by Pigeon J. in Tennessee Eastman, as included on page 119 in the Supreme Court decision do not disregard the findings by Kerr J. in the Exchequer Court. We are guided by the conclusion reached on page 121 by Pigeon J. We read in the remarks by Heald J. in Imperial Chemical Industries that the ratio of Tennessee Eastman is an acceptable basis for refusing a method of medical treatment.

Mr. Smart points to Ciba vs. The Commissioner [1959] S.C.R. saying that the method applied to certain materials may be patentable in producing a new material. The issue was whether making a new and useful product by conventional chemistry was patentable, and in that case was found to be acceptable. We do not equate Applicant's method to a process of conventional chemistry.

Applicant's method in our view, involves the skills of a medical practioner in achieving a satisfactory insertion into a living body of a proper amount of material compatible with the anatomy of the body. We believe the steps clearly point to the performance of a method that resides within the domain of a medical practioner.

In summary, we find that method claims 18 to 26, even though they are couched in terms of being non-surgical, are nevertheless directed to a method of medical treatment, and may not be considered as falling within the ambit of Section 2.

we recommend the rejection of claims 18 to 26 be affirmed for not being directed to patentable subject matter.

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 refuse to grant a patent containing claims 18 to 26. The Applicant has six months within which to appeal this decision under the provisions of Section 44 of the Patent Act.

J.H.A. Gariépy
Commissioner of Patents

Dated at Hull, Quebec
this 15th day of August 1986.