

COMMISSIONER'S DECISION

STATUTORY - Section 2: Pathological Test Process

Method for determination of antigens in an aqueous fluid of a living animal (including humans), not possible by conventional methods, is not a treatment applying medicine to such a living animal; and satisfies the criteria of a "useful" process or art within the definition of Section 2(d) in that it belongs to the manual or productive arts, it is controllable, and it has utility in practical affairs; and a patent therefore is not contrary to the public interest.

FINAL ACTION: Overruled.

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This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated May 10, 1972 on application 003,389. This application was filed in the name of Antonius H.W.M. Schuurs and refers to "Immunochemical Determinations Of Antigens And Antibodies".

In the prosecution terminated by the Final Action the examiner rejected claims 1 to 8 as covering non patentable subject matter under Section 2(d) of the Patent Act.

Claim 1 reads:

Method for the immunochemical determination, by means of an agglutination reaction, of antigens or antibodies in an aqueous solution in which they are present in a concentration too low to be reliably determined by conventional agglutination reaction procedure without prior fractionation or concentration or are attended with factors disturbing to conventional agglutination reactions arising from contaminants present in the aqueous solution to be tested, comprising

- (a) adsorbing one of the immunochemical reaction components selected from the group consisting of antigens and antibodies on carrier particles suitable for antigens and antibodies;
- (b) reacting said component by joining it with the aqueous solution to be tested containing the other reaction component to be determined;
- (c) separating the carrier particles, after the reaction has taken place, from the reaction mixture;
- (d) resuspending the particles in a small volume of a suitable aqueous medium; and
- (e) visually determining the reaction pattern of the carrier particles.

In the Final Action the examiner stated in part:

Applicant's arguments imply that the meaning "Any new and useful art, process, ...." must be given the broadest possible interpretation and any subject matter encompassed by this definition is patentable, unless the Patent Act specifically forbids it. This is not the case, however, as the Patent Office has consistently, over many years held the view that everything that is new and useful is not necessarily patentable and it is well established that there are arts and processes which are definitely excluded from patent protection, some by statute (as in Section 28(3) of the Patent Act) and others by court decisions; for example, methods dependent on professional skill (See Lawson vs. Commissioner of Patents or Tennessee Eastman Co. vs. Commissioner of Patents). In the area of processes the Patent Act is designed to protect those which have novelty, utility, inventive ingenuity and are also susceptible of industrial application

Although the present method for the immunochemical determination of antigens or antibodies may be new, useful and unobvious, it is however not susceptible of industrial application. The method here, which is performed on a non-industrial product, viz., human body fluids, is rather conceived as being essentially non-economic as it does not produce a result in any way associated with trade, commerce or industry in the sense that those expressions have been used in the above particular patent case judgements and is also contrary to the spirit of the expression "working on a commercial scale" referred to in the Patent Act. Therefore, it is deemed not being in the public interest to grant patents for such methods of pathological diagnosis.

In the response of November 10, 1972 the applicant stated in part:

Now applicants will admit that the provisions of Section 2(d) require some qualification which, as the Examiner has correctly put, arise either from the provisions of Section 28(3) of the Patent Act or from court decisions. However, in applicants' view, neither Section 28(3) nor the pertinent decisions of the courts require Section 2(d) to be qualified in such a manner that a patentable process must be "susceptible of industrial application". Rather, applicants would urge that the relevant criteria are more accurately identified by Dickson C.J. in National Research Development Corporation's application (Australia) (1961) RPC 135 where, at page 145, the following statement is made in the judgement:

"The point is that a process, to fall within the limits of patentability which the context of the Statute of Monopolies has supplied, must be one that offers some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art (see Virginia-Carolina Chemical Corporation's Application (1958) R.P.C. 35 at p. 36) that its value to the country is in the field of economic endeavour. (The exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic; see Maeder v. Busch (1938), 59 C.L.R. 684 at p. 706.)"

This passage was referred to in the judgment of Cattanach J. in the decision of the Exchequer Court in Lawson v. Commissioner of Patents. In summary, it appears to be necessary that a patentable

process belongs to a useful art as distinct from a fine art and is not essentially non-economic. These criteria appear to have been accepted by the Office in recent decisions of the Patent Appeal Board.

In applicants' submission, the subject matter of claims 1 to 8 does belong to a useful art as distinct from a fine art or, in the words of the Patent Appeal Board in the decision referred to above, does relate to a manual or productive art as distinct from a fine art. The method steps of the claims comprise those which are set out clearly in claim 1 as steps (a) to (c) inclusive. It is submitted that these steps clearly do not belong to a "fine art" involving the use of professional skills having judgmental content, and are not for instance comparable to methods of surgery and other processes of treating the human body. Moreover, such methods appear most frequently today to be carried out by commercial testing laboratories (clinical laboratories) who bill the customer directly for their services even though in some cases such matters may be covered by medical insurance. Thus, even if the method is not susceptible of industrial application, it certainly is of commercial application and yields a result that is essentially of an economic nature in that such a test procedure is ordered and paid for in the ordinary way of business. Furthermore it is beside the point that the method is performed on a non-industrial product; it is submitted that the relevant criterion is whether the method is susceptible of commercial application.

At the outset the Board observes that the Final Action at the time conformed with Patent Office guidelines relating to the patentability of inventions involving methods of testing of human body fluids, as distinct from such other testing processes as those applied to other natural products, or to industrial products, or to materials used in the manufacture of such products, even though the end result of the test process is not necessarily a physical product in that it may be tangible information only.

The basic issue is whether the subject matter of the process claims 1 to 8 constitutes a "useful art or process" within the meaning of Section 2(d) of the Patent Act defining patentable subject matter, and more particularly whether the subject matter satisfies the principles and criteria applied by jurisprudence dealing with the question. In cases of claims involving methods of testing the established criteria of utility is usually the critical area in determining whether such subject matter is a patentable invention within the meaning of Section 2(d) of the Patent Act. In the present case the prerequisites of novelty and unobviousness are assumed since no objection has been made on such grounds.

Section 2(d) of the Patent Act reads:

"Invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter,

Recently there has been two Exchequer Court cases of particular interest in the interpretation of Section 2(d) of the Patent Act. They are J. Wyburn Lawson v The Commissioner of Patents (1970) 62 C.P.R. 101, which concerns claims to a plot of land subdivided in a certain manner, and Tennessee Eastman v The Commissioner of Patents (1970) 62 C.P.R. 117, which concerns claims directed to a method of surgical bonding of body tissues of human beings.

The question of whether a subject matter is an "art" or a "process" was considered in Re Lawson v Commissioner. In that case "art", "process" and "method" were viewed as one and the same thing, and in any event it was settled that "art" may include a method or process citing Refrigerating Equipment Limited v Waltham Systems Incorporated (1930) Ex. C.R. 154 at 166, wherein Cattanach J. then stated at page 109:

"An art" or operation is an act or series of acts performed by some physical agent upon some physical object and producing in such object some change either of character or of condition. It is abstract in that it is capable of contemplation of the mind. It is concrete in that it consists in the application of physical agents to physical objects and is then apparent to the senses in connection with some tangible object or instrument.

And at page 110 he also stated:

It is now accepted that if the invention is the means and not the end, the inventor is entitled to a patent on the means.

That the process under consideration falls within that meaning of an "art" is a matter of fact in that the process consists in the application of physical chemical agents to a physical solution, the result of which is then apparent in the treated solution, for if there is no physical or chemical change in the character or condition of the solution as a result of applying the process, it would not be possible to determine the reaction pattern of the carrier particles in the solution after, as well as before, the physical or chemical agents performed upon it. On the other hand, In Re Lawson v Commissioner, supra, it was held that as a

result of the process then under consideration, neither the character nor the condition of a material object was in any way physically changed, nor was the user's ability to deal with it in anyway increased or decreased.

The other factor to be decided is whether the "art" in terms of the present process satisfies the prerequisites of being a "useful" art or process within the meaning of Section 2(d), which may be conveniently stated, inter alia as to: whether the subject matter is useful in a "manual or productive art" (as distinct from a fine art such as that in which novelty is solely the exercise of professional skills, or that having intellectual meaning or aesthetic appeal alone), whether the subject matter is controllable and reproducible by the means disclosed so that the desired result inevitably follows whenever it is worked, and whether the subject matter has utility in practical affairs (as that in relation to trade, commerce or industry) which is beneficial to the public.

Since the subject matter of the present process is in the "means", as distinct from the "end", it should be entitled to a patent within the meaning of a manual or productive art as stated In Re Lawson v Commissioner, supra. The fact that the relevance of the end result of the present process may be applied in connection with the treatment of living animals is incidental to the subject matter of the present invention, it is a fact that the present process does not apply any pharmaceutical properties of a substance to affect or employ the physiological processes of a living animal. That patentability should be denied merely because treatment of a living animal is a prerequisite of the usefulness of the end produced is untenable since it would be wide enough to exclude medicines as well as their processes of manufacture intended to be governed by Section 41(1), new and obvious tests for quality assurance of industrially produced pharmaceuticals, and such other inventions intended to have medical and surgical application. The foregoing conforms to the S.C.C.'s decision In Re Tennessee Eastman v Commissioner of Patents, of December 19, 1972

(unreported), (on appeal from the Exchequer Court's decision on the same case, *supra*) when it stated that the process then under consideration of applying a medicine to a human being "...is clearly in the field of practical application" as opposed to a mere scientific principle or abstract theorem excluded by Section 28(3) of the Patent Act.

In the S.C.C.'s decision *Tennessee Eastman v Commissioner*, *supra*, it was held that patents for medical treatment per se must be excluded under the Patent Act in that the use of a medical substance cannot be claimed by a process apart from the process of producing it. In any event the present claims distinguish factually from the claims then under consideration in that no step of medical or surgical treatment is set out in the claims. It is also noted that in this decision the Supreme Court seemed to equate its decision with the latest reported case brought to its attention, In Re Schering A.G.'s Application (1971) RPC 337, a case dealing with a method of contraception, citing the conclusion of the Patent Appeal Tribunal at page 345 as follows:

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 judgement, be allowed to proceed. As Swift's Application (1962) RPC 37 in the Divisional Court of the Queen's Bench Division 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 by the Court)


It is also of interest to note that the material advantage and the economic issues were indicated by the citation of the National Research Development Corporation's Application (1961) RPC 135 in both the Lawson v Commissioner and Tennessee v Commissioner (Exchequer Court), *supra*, wherein it is stated:

The point is that a process, to fall within the limits of patentability which the context of the Statute of Monopolies has supplied, must be one that offers some advantage which is material in the sense that the process belongs to a useful art

as distinct from a fine art (see Virginia-Carolina Chemical Corporations's Application (1958) RPC 35 at p. 36) -- that its value to the country is in the field of economic endeavour.  
(The exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic: see Maeder v Busch (1938) 59 C.L.R. 684 at p. 706).  
(Emphasis added)


The Board is therefore satisfied that the present state of the law provides no basis on which to exclude the present subject matter from patent protection. The subject matter lies in the field of a "useful art" as opposed to a "fine art", "abstract theorem" or "scientific principle". It is an invention which is inherently beneficial to the public, and one which is reproducible and controllable to produce the desired result whenever it is worked or used. Furthermore, it has utility in practical affairs, has commercial application and is not contrary to the public interest.

In the circumstances, therefore, the Board is satisfied that the Commissioner ought not to refuse claims 1 to 8 on the grounds that the subject matter falls outside the statutory requirements of Section 2(d) of the Patent Act, and recommends that the Final Action refusing claims 1 to 8 be withdrawn.

  
J.F. Hughes  
Acting Chairman  
Patent Appeal Board.

I concur with the findings of the Patent Appeal Board and withdraw the Final Action and return the application to the examiner for resumption of prosecution.

Decision accordingly,

  
J.A. Brown  
Acting Commissioner of Patents.

Dated at Ottawa, Ontario  
this 23rd day of March, 1973

Agent for Applicant