

COMMISSIONER'S DECISION

STATUTORY - Section 2(d): Chemical Test Using New Fluorescent Dye

The process of applying a fluorescent dye to the teeth and gums so as to reveal to the naked eye diseased tissue when subjected to light in the specified Angstrom range is a matter of fact within the meaning of "art" which produces a physical change or result; the making and use of which satisfies the pre-requisites of a "useful" invention as have been applied by jurisprudence.

FINAL ACTION: Reversed

This decision deals with a request for review by the Commissioner of Patents of the Examiner's Final Action dated May 16, 1972 on application 880,719. This application was filed in the name of Herbert Brilliant and refers to "Use Of Fluorescent Dyes to Matters In Oral Cavity".

In the prosecution terminated by the Final Action the examiner refused claims 1 to 6 as not patentable under Section 2(d) of the Patent Act, and claims 7 to 9 as not patentable over the prior art:

Canadian Patent:

500,625 Mar. 16, 1954 Alderman et al

In the Final Action the examiner stated in part:

The rejection of claims 1 to 6 is maintained and the reason for such rejection is that not all processes are patentable. The methods of clinical testing in claims 1 to 6 belong to the realm of practising medicine in general and more specific in the professional field of dentistry and surgery and therefore are not patentable under Section 2(d) of the Patent Act.

The rejection of claims 7 to 9 is maintained and the reasons for such rejection is that the subject matter of claims 7 to 9 is not patentably different from the compositions taught by Alderman et al in Canadian Patent 500,625 which teaches an oral cleanser or dentrifice containing a fluorescent substance which fluoresces when exposed to light containing some U.V. radiation e.g. 2920 to 4000 Å units in an aqueous carrier. The amount of the fluorescent dye claimed in claims 7 to 9 is in the range 0.00005% to 5.00% and therefore still incorporates the range of 0.001% to 0.1% claimed in the above mentioned patent. Also the range of wavelength claimed of 3000 to 5000 Å units still incorporates part of the wavelength of the above mentioned patent eg. 2920 to 4000 Å units.

In the response of August 12, 1972 the applicant stated in part:

The Examiner has cited Canadian patent 500,625 against claims 7 to 9. These claims have been amended to remove the objectionable subject matter, and in particular, claim 9 (old claim 7) has been amended to restrict the lower limit of fluorescent dye and the remaining claims also contain such restrictions as well as an amended lower limit of wave length frequency in the case of claim 11. It is submitted that the amended claims define patentable subject matter over patent 500,625. This reference is directed to the use of alkaline aqueous carrier which is not the case in the present invention. The range of fluorescent dye in the cited reference as stated by the Examiner at the top of page 2 of the official action of May 16th is 0.001% to 0.1%. The new composition claims contain restrictions as to the amount of fluorescent dye and frequency of light wave exposure, all being outside the range referred to in the Alderman cited patent.

Corresponding amendments have been made to method claim 1 and new method claims 2 and 3 have been added containing revised ranges.

Reconsideration of the Examiner's rejection of claims 1 to 6 is also respectfully requested. The reason given in the official action for the rejection is "that not all processes are patentable". This may well be the case, but applicant submits that method claims 1 to 8 are patentable in the present situation.

The Examiner has also suggested that inventions in the "realm of practising medicine in general and more specific in the professional field of dentistry and surgery" are not patentable. Applicant knows of no Canadian law prohibiting such inventions, and in any event, as is clear from the enclosed brochure the method of new claims 1 to 8 is not in the "professional" field of dentistry since it is intended to be carried out by the non-professional user.

It is submitted that the invention defined in the method claims 1 to 8 is distinguishable from the Exchequer Court case of Tennessee Eastman v. The Commissioner of Patents 62 C.P.R.117. That case was directed to claims primarily for a method of treatment of human bodies, namely the surgical bonding of tissues. In the present case the applicant's invention is not "treating" human bodies as discussed above.

This invention relates to means for making visible to the naked eye pathological conditions on topical areas of the human body. More particularly, it has reference to means for making readily visible tumors, epithelial aberrations and the like which exist in or near the external body tissues, as well as plaques, microcosms, tartar, leaky dental fillings and dental decay. The composition of the solution used is also claimed. Claim 1 and claim 9 which are representative of the invention read:

Claim 1:

A method of making visible to the naked eye the presence of disease-causing foreign matter in the oral cavity of a living human being, comprising, applying a composition consisting

essentially of water in which is dissolved from about 0.00005% to about 5.0% of a non-toxic, pharmaceutically acceptable fluorescent dye, to the areas suspected of having disease-causing foreign matter and to the areas adjacent thereto having relatively no such foreign matter, and bathing both areas in light whose wave length has a frequency within the range of between about 5000 and 5200 Angstrom units, whereby the two areas are sharply delineated as the one of said areas which contains the foreign matter is caused to glow with the color of the fluorescent dye while the other remains substantially un-illuminated.

Claim 9:

A composition which may readily be applied to the various areas of the oral cavity of a living human being in order to make visible to the naked eye the presence of disease-causing foreign matter therein, said composition consisting of water in which is dissolved from about 0.2% to about 5.00% of a non-toxic, pharmaceutically acceptable fluorescent dye which, when it comes into contact with areas having disease-causing foreign matter and areas adjacent thereto having relatively no such foreign matter, and both areas are bathed in light whose wave length has a frequency within the range of between 3000 and 5200 Angstrom units, causes the two areas to be sharply delineated as the one of said areas which contains the foreign matter is caused to glow with the color of the fluorescent dye while the other remains substantially un-illuminated.

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 involving the human body, 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 amended process claims 1 to 8 constitutes a "useful art or process" within the meaning of Section 2 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 of the Patent Act. In the present case there is no need to consider novelty and unobviousness of the process claims since no objection has been made on such grounds.

Section 2 of the Patent Act reads in part:

"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 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.

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. And later at page 109 Cattanach J. stated:

"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 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 the meaning of an

"art" is a matter of fact, for the process consists of the application

of a fluorescent dye to the teeth and gums which produces a physical

change in character of the result to be achieved when subjected to

light in the specified frequency range.

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, 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 ~~the~~ effect a curative or preventive treatment of an ailment. 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 an adhesive substance to body tissues "... 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 concluded 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 referred to in 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.... (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 (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"; it is an invention which is inherently beneficial to the public; one which is reproducible and controllable to produce the desired result whenever it is worked or used, and it has utility in practical affairs.


In the circumstances, therefore, the Board is satisfied that the Commissioner ought not to refuse amended claims 1 to 6 on the grounds that the subject matter falls outside the statutory requirements of Section 2 of the Patent Act, and recommends that the refusal on this ground be withdrawn.

The second ground of rejection that claims 7 to 9 are too broad in scope is well taken, however, the applicant has presented amended claims 9 to 13 in an attempt to overcome the cited art.

The cited patent (500,625) relates to an oral cleansing agent in the form of a dentifrice containing a fluorescent substance in a slightly alkaline, aqueous carrier. The disclosed operable concentration of the fluorescent substance was 0.001 to 0.1%, furthermore, the purpose and function of the fluorescent substance was to create an optical illusion of greater whiteness to the teeth.

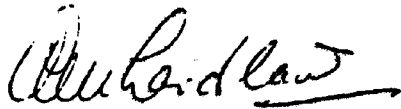
In contrast, the composition of the current application consists solely of an aqueous solution of a fluorescent dye in the concentration range of 0.2 to 5.0%. The purpose of the fluorescent dye is to differentiate between healthy and unhealthy tissues or teeth when exposed to the appropriate activatable light rays for the dye. There is, however, no teaching in the reference that the alkaline, aqueous solution of the fluorescent dye could be used for the purpose intended by the applicant.

The Board is therefore satisfied that amended claims 9 to 13 avoid the cited prior art, however, some consideration should be given to amended claims 1 to 8 in view of the cited prior art.


J.F. Hughes
Assistant Chairman
Patent Appeal Board.

I concur with the findings of the Patent Appeal Board and withdraw the ground of rejection under Section 2 of the Patent Act, and accept claims 9-13 as avoiding the cited prior art. The application is returned to the examiner for resumption of prosecution.

Decision accordingly,

A handwritten signature in dark ink, appearing to read "A.M. Laidlaw", with a long horizontal flourish extending to the right.

A.M. Laidlaw
Commissioner of Patents.

Dated at Ottawa, Ontario
this 16th day of April, 1973

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