COMMISSIONER'S DECISION

STATUTORY-LIVING MATTER: Products Comprising Living Microorganisms

Inventions have equal status in satisfying the prerequisites of patentability whatever the nature of the subject matter. Novelty and unobviousness were not grounds of objection. The vaccine composition comprising living virus is in no sense a fine art and lies in a useful art. The attenuation of the natural activity of the virus is produced and controlled by the intervention of man, and the vaccine composition inevitably follows the conditions disclosed for its production; thus the prerequisites of utility are satisfied and the application ought not to be refused by the Commissioner (in re Vanity Fair).

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 October 28, 1971 on application 950,086. This application was filed in the name of Behringwerke Aktiengesellschaft (Othmar Ackermann) and refers to "Vaccine Against Distemper And Process For Its Preparation".

In the extended prosecution terminated by the Final Action the examiner refused the application because the process of attenuating a live virus and the modified living product of such a process, which form the subject matter of the claims, do not represent a patentable invention according to Section 2(d) of the Patent Act.

In the Final Action the examiner stated in part:

(a) Section 2(d) of the Patent Act provides a definition of the term "invention"; it does not affirm that an invention is necessarily patentable. The requirements for patentability are not confined merely to novelty and utility. The courts, in interpreting Section 2(d), have laid down that, for instance, unobviousness is also an essential condition. Moreover, Section 28(3) introduces a further qualification by stating that no patent shall issue for certain types of invention. It follows therefore that, taken literally, Section 2(d) does not set forth all the requisites for patentability and must be more narrowly construed than the wording would suggest.

(b) The creation of living things such as new plant varieties, cross breeds of animals, viruses, bacteria and the like, and the results of such creation do not fall within the scope of subject matter to which patentable protection may extend.

(c) The case of the Commissioner of Patents vs Ciba Ltd., which the applicant has invoked in support of his arguments, relates to situations where a known process may acquire patentable merit by virtue of the patentability of the product. In the present issue the product itself is unpatentable and the case is therefore irrelevant.

The applicant in his response of January 28, 1972 stated in part:

> It is the applicants' belief that the application is not open to objection on the grounds stated by the Examiner. Applicants agree with the third paragraph of the Official Action wherein the Examiner has stated that the definition of the expression "invention" must be construed in somewhat narrower terms than those set out in Section 2 of the Act. However, where the applicants and the Examiner differ is in who has the authority to make this construction. Applicants believe that construing of the Act is solely the province of the courts; the Examiner apparently believes that is within his authority to make such a construction.
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> It is the applicants' contention that the Examiner has completely ignored two relevant pieces of jurisprudence throughout the prosecution of this case.
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> In American Cyanamid Co. v. Charles E. Frost & Co. (1965) 2 Ex. C.R. 355, patents to the antibiotics tetracycline and chlortetracycline were held to be valid and infringed. The latter was formed by placing micro-organisms in a fermentation broth containing chloride ions while the former can be formed either by dechlorinating the latter or by placing a micro-organism in a nutrient broth with a controlled chloride content.
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> Similarly in the case Parke, Davis & Co. v. Laboratoire Pentagon Ltée., 37 Fox P.C. 12, a patent for Chloramphenicol was held valid. This product was prepared by a stepwise process which included both a biological step and a physical step but it did not include a chemical step.
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> There are many analogies which can be drawn between the antibiotic of Parke, Davis patent and the vaccine claimed here. They are both vendible products, they are both prepared by biological and physical processes and they both have therapeutic properties. Both the antibiotic and the vaccine in their pristine product state are substantially inert. It is in use that their separate therapeutic properties which may be manifested by chemical or biological reactions are exhibited. However it is not such use which is being claimed; it is the product in its pristine state which is claimed.
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> The Examiner appears to be rejecting the product claims on the basis that the attenuated virus therein, can undergo further biological reaction. However in the state in which it is claimed it is substantially inert. That it might undergo further biological reaction in use is irrelevant. To be consistent, the office would have to reject claims to any substance which is capable of further reaction. To take a spectacular example, a claim to an explosive compound would have to be rejected because the explosive remains inert under only a very narrow range of conditions and the risk of disintegration may be quite high. However there is no doubt that new and unobvious explosives are patentable.
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> In summary, the Examiner has not shown that there is any substantial difference between an antibiotic and the vaccine claimed. Without such a showing the Examiner completely ignores jurisprudence and construes Section 2(d) in opposition to the construction made thereupon by the courts. The Examiner has failed to make a case against the vaccines being claimed and applicants feel that the rejection which he has raised should be withdrawn.

This invention relates to a vaccine against distemper containing a live, attenuated, distemper virus, as well as the process for the manufacture of such a vaccine. Claims 1 and 6 read as follows:

Claim 1 - A process for the manufacture of a vaccine obtained from a distemper virus attenuated by at least 50 successive passages in the culture tissues of dogs' organs, for the immunization of mustelines against distemper, process wherein the attenuated distemper virus is passed through at least 10 successive passages in the culture tissues of mustelines.

Claim 6 - A vaccine for the immunization of mustelines against distemper, characterized by a content of distemper viruses which have been attenuated by at least 50 successive passages in culture tissues of dogs' organs, and which have then been passed through at least 10 successive passages in the culture tissues taken from the tissues of mustelines.

At the outset the Board would like to make it clear that the Examiner's actions in this case were in conformance with Patent Office guidelines relating to the patentability of inventions involving living matter.

Of fundamental importance is the difference between discovery and invention. Creations or products under the laws of nature are regarded as being mere discovery; the existence of which man may discover but which he could not have invented. As utility is a prime requisite of a patentable invention, nothing is invented that can be the subject of a patent until a discovery or a formulation of an idea of an end has been united with a mode of application so as to produce useful results (Gerrard v. Carey, (1926) Ex. C.R. 170 at 178), in terms of either a new and useful thing or result or a new mode of producing an old thing or result (Lane-Fox v. Kensington & Knightsbridge Electric Lighting Co. (1892) 9 R.P.C. 413 at 416.

Jurisprudence and long standing practice has established that subject matter based on the discovery of a vital process, force or phenomenon of nature, can be the basis of patentable subject matter, provided some artificial result or effect is produced and controlled by the intervention of man, even though it depends partly or mainly upon the function or result produced by living matter, and provided it is practically useful even though solely in connection with an inherent response of a living thing.

In Continental Soya v. Shorts Millings (1942) 2 Fox Pat C 103 the Supreme Court of Canada held that: "... manufacture or composition of matter in Section 2(d) of the Patent Act includes a product, which, as well as the process by which it is obtained, may be patentable, if it is

new and useful." The subject matter at issue in this case depended upon the use of an enzyme as a bleaching agent in a process for making bread. This is held to be a manifestation of man's control over the use of the enzyme in a process. In any event the Supreme Court held that the use or effect of the enzyme was entitled to the same protection as the use or effect of the hormone in the Banting patent.

In American Cyanamid v. Frosst (1965) 2 Ex. C.R. 355, the claims in dispute involved living matter and, although numerous defences were raised by the alleged infringer, the patentability of the antibiotic was not in contest. The decision of Mr. Justice Noël in this case describes at length the production of antibiotics made by processes including living matter; yet whether it is subject matter proper for a patent was not questioned.

Finally, in the Parke Davis v. Laboratoire Pentagone S.C.C. (1968) 37 Fox Pat. C. 12, the Supreme Court of Canada considered an appeal dealing with the infringement of a patent for an antibiotic which was produced by a living micro-organism known as streptomyces venezuela. Again, there was no question as to the patentability of such subject matter. Moreover, the practice of United States, Great Britain and other major Patent Offices is to patent such inventions and the Courts have not been reluctant to support the validity of these patents.. Also, of significant importance in this decision the Supreme Court of Canada held that, a chemical substance prepared by a fermentation process followed by purification of the substance with chemical solvents, or by absorption, is a product of a chemical process within the meaning of Section 41(1) of the Patent Act.

Consequently, the basic question which must be decided is whether the subject matter of this application falls within Section 2(d) of the Patent Act and satisfies the well established prerequisites which apply to the subject matter of a patentable invention whatever the nature of the subject matter, and it can be taken as settled that each kind of subject matter has equal status and rights as a patentable invention unless the statute dictates otherwise; e.g. Section 41(1) of the Patent Act. That is, the principles and criteria governing what is a patentable

invention within the definition must be applied equally, not piecemeal, in respect of every kind of subject matter.

The term living organism, in its broadest and most popular definition, covers every self-synthesising or self-reproducing organic entity from complex mammals down to the simplest organism. But, it is a disputed question among experts as to whether viruses do in fact fall within this category in view of their non-cellular structure and lack of a metabolic system, features which distinguish them from all other organisms, and, according to some opinions, justify defining them as inanimate forms of matter. However, since they share with the higher organisms the nucleic acid mechanism of genetical replication, and can be deemed to have delegated their metabolism to the cells which they parasitize, there are sufficient grounds for regarding them for present purposes as living even though decidedly border line.

As of interest, in Swifts & Co.'s application (1962) R.P.C. 37, the court found that the British Patent Office did not have authority to reject an application for a method for tenderizing meat comprising the injection of enzymes into animals before slaughter.

Also, of interest, in Virginia-Carolina Chemical Corporation application (1958) R.P.C. 36, the court held:

> At one time it seems to have been thought that any operation which involved living organisms was excluded from the definition of invention. That this was unjustified is apparent from the judgment in Commercial Solvents Corporation v. Synthetic Products Coy., (1926) 43 R.P.C. 185, and from the considerable number of patents granted in respect of the preparation of antibiotics. The increasing use of naturally occurring organisms for initiating or controlling or modifying manufacturing operations has wholly outmoded as a rule of thumb guide a restriction of patentability to inanimate matter. In the case of Standard Oil Development Company's Application, (1951) 68 R.P.C., p. 114 (See p. 115 at line 53), I suggested a test which may be useful, namely, an isolation of the end product of the alleged invention. If to secure this the development of living animal or vegetable matter by the operation of natural laws is essential, the applicant cannot claim to have invented it nor the means of procuring it.

The prerequisite of novelty, an objective consideration, need only be considered to establish what the subject matter in question is, having regard to the state of the related prior art, and is not in question in the present case. Also the prerequisite of unobviousness, a subjective consideration, is not in question in the present case. In the case at point, involving living micro-organisms, utility is usually the critical

prerequisite to be considered, particularly as to whether the vital activity of the subject matter can be controlled and put to practical use by the intervention of man.

The established criteria of a useful invention (utility) are whether the subject matter is practically useful in a useful art (manual or productive) as distinct from the fine art (practising professional skills having judgemental content, intellectual meaning and aesthetic appeal), and particularly whether it is operable (reproducible and controllable) so that the desired result inevitably follows whenever the subject matter is worked or used by its users. Moreover, the subject matter must be beneficial to the public. (Wandscheer v. Sicard, (1946) Ex.C.R. at 112 and (1948) SCR 1; and Mailman v. Gillette Safety Razor, (1932) Ex.C.R. at 54 and (1932) SCR at 724).

On a consideration of the application at hand the subject matter is in no sense to be considered a fine art, and lies in a useful art (manual or productive). Moreover, any advance in this field is inherently beneficial to the public provided it can be controlled.

Hence, the critical question in the present case is whether the subject matter is operable (reproducible and controllable). In the present case the activity of micro-organisms is created in an environment established by the hand of man through a series of cultivations and treatments in a controlled manner. It is also established that the vaccine can be produced in a manner as disclosed in the specification, for when given the micro-organisms and the appropriate conditions the desired result is produced; thus enabling a person skilled in the art to produce the invention after the monopoly expires. On this point and of significance is the principle set out by the Court in N.R.D.C's application (1961) R.P.C. 147 that: "A distinction has necessarily to be drawn between cases of this class (plants) and cases of methods employing micro-organisms; ... for in the latter class of cases the process is analogous to a chemical process in that, given the micro-organisms and the appropriate conditions, the desired result inevitably follows from the working of the process: see Szuec's case (1956) R.P.C. 25." (emphasis added)

Of importance is the responsibility of the Commissioner of Patents as held by the Supreme Court of Canada, in Vanity Fair v. Commissioner of Patents (1939) S.C.R. 24 at 28, that: "The Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation." (emphasis added)

In the circumstance, therefore, assuming novelty and unobviousness, the Board is satisfied, having regard to the present state of the law, that the Commissioner ought not to refuse this application since there is no apparent reason to exclude the subject matter from patent protection, as not within the meaning of invention under Section 2(d) of the Patent Act.

The Board recommends that the decision of the examiner, to refuse the application on the grounds that it does not represent a patentable invention according to Section 2(d) of the Patent Act, be withdrawn and that consideration be given as to whether the vaccine product claimed is governed by Section 41(1) of the Patent Act. Attention is directed to the Supreme Court of Canada's decision, Parke Davis v. Laboratoire Pentagone, as noted herein.

J.F. Hughes,
Acting Chairman
Patent Appeal Board

I concur with the finding of the Patent Appeal Board and withdraw the Final Action and return the application to the examiner for resumption of prosecution, including consideration under Section 41(1) of the Patent Act.

A.M. Laidlaw
Commissioner of Patents

Dated at Ottawa, Ontario
this 18th day of September, 1972.

Agent for Applicant

Fetherstonhaugh & Co., Ottawa.