IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 484,723, having been rejected under Subsection 47(2) of the Patent Rules, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has consequently been considered by the Commissioner of Patents.

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This decision deals with the Applicant's request for a review of the Examiner's Final Action on patent application number 484,723 (Class 195-1.22) which was filed on June 21, 1985 for an invention entitled "TRANSGENIC ANIMALS". The inventors are Philip Leder and Timothy A. Stewart and the application was assigned to the President and Fellows of Harvard College. The Examiner in charge issued the Final Action on March 24, 1993 refusing claims 1 to 12 and declaring claims 13 to 26 to be allowable. The Applicant replied on September 24, 1993 requesting a review by the Commissioner of Patents and an oral hearing before the Patent Appeal Board and subsequently a hearing was held on July 28, 1994 at which Joy Morrow represented the Applicant. I have subsequently reviewed the prosecution of the application and discussed the rejection with the Board before rendering my decision.

The application is directed to a transgenic mammal, in particular a transgenic mouse which can be used as a test vehicle for substances suspected of being carcinogenic or for substances thought to confer protection against the development of neoplasms.

The inventors have constructed myc gene-containing plasmids by deleting selected regions from a specific plasmid and replacing them with myc regions to construct the required plasmid. Copies of the linearized myc gene-containing plasmid are injected into the male pronucleus of fertilized one-cell mouse eggs derived from matings between C57BL/6J and CD-1 types of mice. The injected eggs are transferred into pseudo-pregnant foster females and allowed to develop to term. Introducing the myc gene sequence at the fertilized one-cell egg stage ensures that the gene will be present in all of the germ cells and the somatic cells of the transgenic animal.

Offspring are tested for the retention of the injected sequences by Southern blot analysis of DNA extracted from the tail. Several offspring referred to as founder mice, were found to have integrated the myc gene. The presence of the myc gene in the germ cells of the transgenic founder animal in turn means that all the founder animal's offspring that inherit the gene will carry the gene in their germ cells and somatic cells. The founder animals were then mated to uninjected mice and analysis of the DNA of the resulting transgenic offspring indicated that the injected oncogene was transmitted through the germline in a ratio consistent with Mendelian inheritance of single loci.

The application contains 26 claims with claims 1 to 12 being directed to transgenic mammals and claims 13 to 26 being directed to processes for producing the transgenic mammals, to the transgenic cell culture and a process for producing it, to various plasmids bearing the oncogene and towards the use of the invention to test a material suspected of altering neoplastic development in a mammal. Claims 1, 11 and 12 which are representative of the rejected claims are as follows:

> 1. A transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.
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> 11. The mammal of claim 1, said mammal being a rodent.
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> 12. The mammal of claim 11, said rodent being a mouse.

In his rejection of claims 1 to 12 the Examiner stated, *inter alia*, that the Commissioner has both a right and an obligation to consider the public interest in the granting of a patent. There is some implication in this interpretation of the Commissioner's duty under the *Patent Act* that the Commissioner can decide that a particular invention can be found unpatentable as a matter of policy or discretion rather than as a result of an interpretation of the provisions of the Act.

In this regard the Commissioner's duty is clear from the statement of the Supreme Court in Monsanto Co. v. Commissioner of Patents 42 C.P.R. (2d) 161, addressing section 40 (then section 42) of the *Patent Act* at page 177, that:

> In this respect it is important to note that s. 42 of the *Patent Act* reads:
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> > 42. Whenever the Commissioner is satisfied that an 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 therefor.
>
> 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. Commissioner of Patents*, [1938] 4 D.L.R. 657, [1939] S.C.R. 245 at p. 246:
>
> > No doubt the Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation.

I note also that in the case relied on by the Examiner, Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning 41 C.P.R. 9 there is no suggestion in the decision that it was based on anything other than an interpretation of the *Patent Act* as to what constitutes

an invention, the Court stating, at page 17, that:

> .....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.

It follows that in order to reject an application as being directed to unpatentable subject matter, I must be satisfied that by law the applicant is not entitled to a patent and be able to give reasons based on an interpretation of the *Patent Act* and any applicable jurisprudence.

The issue that I have to decide is therefore whether or not claims 1 to 12 of the application claiming non-human mammals are directed to patentable subject matter as defined by Section 2 of the *Patent Act* which reads follows:

> "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;

This definition refers to five categories of invention, clearly the first three, "art", "process" and "machine" are inapplicable when considering claims directed towards a non-human mammal prepared using the techniques of genetic engineering.

The patentability of inventions involving genetic engineering has been considered by the Supreme Court in Pioneer Hi-Bred Ltd. v. Commissioner of Patents 25 C.P.R. (3d) 257. The Court identified two types of genetic engineering (at page 263). The first type involves crossing different species or varieties by hybridization, altering the frequency of genes over successive generations, this being the method by which Pioneer Hi-Bred's new variety of soybean was produced. The second type is that which requires a change in the genetic material, an alteration of the genome affecting all the hereditary material since the intervention occurs in the gene itself at the molecular level. While the first type of genetic engineering implies an evolution based strictly on heredity and Mendelian principles, the second employs a sharp and permanent alteration of hereditary traits by a change in the quality of the genes. In conclusion the Court stated on page 264 that:

> The intervention made by Hi-Bred does not in any way appear to alter the soybean reproductive process, which occurs in accordance with the laws of nature. Earlier decisions have never allowed such a method to be the basis for a patent. The courts have regarded creations following the laws of nature as being mere discoveries the existence of which man has simply uncovered without thereby being able to claim he has invented them. Hi-Bred is asking this court to reverse a position long defended in the case-law. To do this we would have, *inter*

> *alia*, to consider whether there is a conclusive difference as regards patentability between the first and second types of genetic engineering, or whether distinctions should be made based on the first type of engineering, in view of the nature of the intervention. The court would then have to rule on the patentability of such an invention for the first time.
>
> In view of the complexity presented by the question as to the cases in which the result of genetic engineering may be patented, ..., and since I share the view of Pratte J. that Hi-Bred does not meet the requirements of s. 36(1) of the Act, I choose to dispose of this appeal solely on the latter point.

It is apparent that the Supreme Court deliberately chose not to decide whether the soybean resulting from artificial cross-breeding was a patentable invention under Section 2 of the Act.

I do note however, although *obiter*, the Court commented on the patentability of creations that occur in accordance with the laws of nature. It suggests that creations of the reproductive process have never been allowed to form the basis of a patent because they are following the laws of nature, they are mere discoveries the existence of which man has simply uncovered.

I now turn to the Federal Court of Appeal decision in Pioneer Hi-Bred 14 C.P.R. (3d) 491, which did consider the refusal of the application on the grounds that a cross bred variety of soybean was not a manufacture or composition of matter within the meaning of Section 2 of the Act. The Court considered the decision of the U.S. Supreme Court in Diamond v. Chakrabarty (1980), 447 U.S. 303 in examining the expressions "manufacture" and "composition of matter" as they appear in s. 2 of the Patent Act and noted:

> ...especially to the following definitions relied upon by the United States Supreme Court in Chakrabarty:
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> > manufacture : the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties or combinations whether by hand labor or machinery
> >
> > composition of matter : all compositions of two or more substances and ... all composite articles whether they be the result of chemical union or of mechanical mixture, or whether they be gases, fluids, powders or solids.
>
> I have not been convinced. Even if these definitions were held to be applicable to a micro-organism obtained as a result of a laboratory process, I am unable to go further and accept that they can also adapt to a plant variety produced by cross-breeding. Such a plant cannot really be said, other than on the most metaphorical level, to have been produced from raw materials or to be a combination of two or more substances united by chemical or mechanical means. It seems to me that the words "manufacture" and "composition of matter" would be distorted if a unique but simple variety of soybean were to be included within their scope.

The Federal Court of Appeal also noted that plant breeding was well established when the *Patent Act* was passed so that if a new plant variety had been intended to be included in the definition of invention, Parliament would have included special provisions in the statute. The Court summarized their finding as follows, at page 497:

> In sum, relying on the common meaning of the words of the definition of "invention" as it appears in the Act and on the legislative context in which they are found, in so far as the intention of Parliament may be derived therefrom, I am satisfied that the soybean variety developed by the appellant cannot be the subject-matter of a patent of invention.

In his Final Action, the Examiner stated that he was bound by the Federal Court of Appeal decision in the Pioneer Hi-Bred case. However the Applicant has argued that the Examiner is not bound by that decision since the Supreme Court made its decision on grounds different from those used by the Federal Court and also on a different factual basis. In support of its argument the Applicant has referred to the decision in R. v. Secretary of State for the Home Department, ex parte Al-Mehdawi [1989] 1 All E.R. 777 where it was held that where the House of Lords had decided that an issue which was argued in the Court of Appeal was not required to be decided on appeal to the House and where the House expressed no view as to the soundness or otherwise of the Court of Appeal's reasoning on that issue, the Court of Appeal's decision on that issue was not binding on another division of the Court of Appeal.

Since the situation in the Pioneer Hi-Bred case is similar to that in the Mehdawi case in that the Supreme Court decided the appeal in Pioneer Hi-Bred on different grounds than those used in the Federal Court, I agree with the Applicant that the Federal Court decision in Pioneer Hi-Bred is not binding on me, or on the Examiner. I do however note that the Mehdawi case stated (at page 781) that, while the lower court decision was not binding, it was of high persuasive influence on subsequent decisions.

My predecessor had to consider claims directed towards micro-organisms in Re Application of Abitibi Co. 62 C.P.R. (2d) 81 wherein the invention related to microbial cultures taken from domestic and modified or acclimated sulfite liquor. The Commissioner was satisfied that micro-organisms such as yeast, mold, fungi, bacteria, actinomycetes, unicellular algae, virus or protozoa can be the subject of patent protection. However, the Patent Appeal Board, on whose recommendation the Commissioner's decision was based, was reluctant to consider claims to higher life forms patentable stating, at page 90, that:

> If an inventor creates a new and unobvious insect which did not exist before (and thus is not a product of nature), and can recreate it uniformly and at will, and it is useful (for example to destroy the sprūce bud worm), then it is every bit as much a new tool of man as a micro-organism. With still higher life forms it is of course less likely that the inventor will be able to reproduce it at will and consistently, as more complex life forms tend to vary more from individual to individual. But if it eventually becomes possible to achieve such a result, and the other requirements of patentability are met, we do not see why it should be treated differently.

In its argument the Applicant has referred to the practice before the United States Patent and Trademark Office pointing out that its corresponding United States application issued on April 12, 1988 as patent number 4,736,866 containing claims to a transgenic non-human mammal. The definition of invention in the U.S. which is embodied in 35 U.S.C. s. 101 employs language which is very similar to that found in s. 2 of the *Patent Act*. Since the statutory definitions of invention used in both countries are so similar, the Applicant argued that I should follow the same practice with regard to life forms as is followed in the United States. I do not however consider that much weight can be given to United States practice in interpreting Canadian legislation.

In my view the words "manufacture" and "composition of matter" as found in Section 2 apply to something that has been made under the control of the inventor. In the case of "manufacture" it is the production of articles for use from starting materials, prepared by giving these materials new forms, qualities, properties or combinations whether by hand labour or machinery. As to the term "composition of matter" I would construe the term broadly to include not only the result of chemical union or mechanical admixture but also microbiological, or genetic engineering techniques so long as they are performed and controlled by the human hand. At the same time the resulting product must be reproducible in a consistent manner.

What the inventors have done in the instant application is to genetically engineer myc gene containing plasmids which are thereafter injected into the mouse eggs which in turn are injected into the female mouse and allowed to develop to term. To my mind there are two distinct phases involved, firstly the preparation of the genetically engineered plasmid and secondly the development of a genetically engineered mouse in the uterus of the host mouse. In the first phase it is human intervention that controls the production of the plasmid by choosing the necessary enzymes and processing conditions to make the plasmids. In the second phase it is the laws of nature that take over to produce the mammalian end product. In my view different

considerations apply between claims to the lower life forms of the Abitibi decision and the higher life forms claimed in the instant application.

Since the plasmids and the transgenic unicellular material are produced under the full control of the inventor and are reproducible, I am satisfied that they are a "manufacture" or a "composition of matter" under Section 2 of the Act. I note that no objections, based on Section 2, were raised against such claims in the instant application.

However I cannot extend the meaning of "manufacture" or "composition of matter" to include a non-human mammal. On the plain and ordinary meaning of the words, and here I am strongly influenced by the Federal Court of Appeal decision in Pioneer Hi-Bred, I do not find that a non-human mammal like a mouse falls within the definition of "invention". The inventors do not have full control over all the characteristics of the resulting mouse since the intervention of man ensures that reproducibility extends only as far as the cancer forming gene.

Having regard to the above and in applying the test enunciated in Section 40 of the Act, I am satisfied that the Applicant is not by law entitled to be granted a patent containing claims 1 to 12 and therefore I refuse to grant a patent containing these claims on this application.

M. Leesti
Commissioner of Patents

Dated at Hull, Quebec
this 4th day of August 1995