COMMISSIONER'S DECISION

Medical Treatment: The claims to a medical treatment were replaced by use claims, overcoming the rejection. As the use claims were not in issue, the application was returned to the examiner. Rejection modified.

This decision deals with the Applicant's request that the Commissioner of Patents review the Examiner's Final Action on application 480,865 filed May 6, 1985, (Class. 167-165). Assigned to Merck & Co., Inc., it is entitled ENCAPSULATED MOUSE CELLS TRANSFORMED WITH AVIAN RETROVIRUS-BOVINE GROWTH HORMONE DNA, AND A METHOD FOR ADMINISTERING BGH IN VIVO. The inventors are J.L. Kopchick, F.C. Leung, T.J. Livelli, R.H. Malavarca. The Examiner in charge issued a Final Action on October 7, 1988 refusing to allow the application to proceed to patent.

In the response to the Final Action, the Applicant submitted an amended set of seven claims to replace those on file. In a subsequent letter dated April 5, 1990, following a telephone discussion with the Patent Agent, further amendments were made to claims 1 to 3 in the above set of claims.

The application is directed to the use of certain recombinant DNA molecules having an avian retroviral long term repeat ligated to a bovine growth hormone (BGH) that are co-transformed into a mammalian cell culture to obtain a stable cell culture that secretes BGH. To obtain secretion, the transformed mammalian cells are encapsulated in hollow fiber units and implanted into animals.

In refusing claims 1 to 3 in the Final Action for failing to satisfy Section 2 of the Patent Act, the Examiner said, in part, as follows:

. . .

Claims 1 to 3 are rejected as being directed to a method of medical treatment which is outside the definition of invention as given in Section 2 of the Patent Act. (See Tennessee Eastman v. Commissioner of Patents (1974) S.C.R. 111). The subject matter of applicant's claims 1 to 3 are directed to a process of in vivo implantation in animals for the purpose of enhanced animal growth and/or enhanced animal milk production. This implantation results in a modification of the organic functions of an animal and therefore is included under the broad term "medical treatment".

The subject matter of claim 1 is to the "method of increasing milk production in cows by in vivo implantation in said cows of an effective amount of an encapsulated cell line". Claims 2 and 3 are to "the method of increasing animal growth by implantation in vivo in said animals an effective amount of an encapsulated cell line". These two methods of implantation come under the broad term "medical treatment" and therefore are rejected as being outside the definition of invention as given in Section 2 of the Patent Act.

In his letter dated July 25, 1988 applicant argues "the claims 1 to 3 of the present invention are not directed to a medical treatment, contrary to the claim involved in the Tennessee Eastman decision. Neither production of milk nor enhancing milk production is a disease. Thus, the claimed treatment does not effect any disease state and is therefore not a medical treatment." The examiner begs to differ. The subject matter of claims 1 to 3 are to "in vivo implantation" which results in enhanced milk production and/or animal growth. In vivo implantation is a treatment method which results in a change of the metabolism of the animal. The policy of the office is to interpret the word "medicine" in a broad sense i.e. "the science and art concerned with the cure, alleviation and prevention of disease, and with the restoration and preservation of health". It has been held by the Commissioner in Commissioner's decisions published in the C.P.O.R. on December 20, 1977 and on May 23, 1978 that treatment of animals is not patentable.

. . .

In the response to the Final Action, the Applicant argued, in part, as follows:

. . .

The Examiner is well aware that any policy of the Patent Office is not cut in stone and thus is susceptible to change. As an example, the attention of the Examiner is drawn to the fact that the definition of medicine includes "diagnostic agents" and accordingly, one is led to believe that a method of administering a diagnostic agent to a human for the purpose of localizing a tumor would be directed to a method of treatment and thus not patentable. Yet the Examiner has to be aware of the decision rendered by the Appeal Board in the application for patent of Goldenberg which subsequently led to Canadian Patent 1,244,344.

In the Goldenberg patent, the Examiner also referred to tne fact that anything injected into a human body will change its metabolism and thus constitute a medical treatment ... yet with the Goldenberg decision, ... this is no longer valid.

. . .

What should be considered here, is whether the method claims 1-3 lead to a vendible product. Morton, J. expressed clearly certain rules which apply to the patentability of method of treatment claims in **In Re Application for a Patent by G.E.C. (1942) 60 R.P.C. 1** where at page 4, he stated as follows:

> "... In my view a method or process is a manner of manufacture if it (a) results in the production of some vendible product, or (b) improves or restores to its former condition a vendible product, or (c) has the effect of preserving from deterioration some vendible product to which it is applied. In saying this, I am not attempting to cover every case which may arise by a hard and fast rule." (underlining ours)

. . .

The improved vendible product in the present case is a cow which will provide more milk or a steer which will be heavier when taken to the slaughter house.

With the Tennessee decision, every method which consisted of administering some product to the human or animal body was considered a method of treatment not included within the scope of the definition of invention in Section 2 of the Patent Act. The administration of any product falling within the definition of "medicine" as set out in the ICI case was refused on the basis that it constituted a "medical treatment."

. . .

... in (a) recent decision ... a method which comprised the injection of an antibody for the detection and localization of a tumor was allowed in C.P. 1,244,344. The decision ... is dated May 13, 1988 which is about five months prior to the issuance of the Final Action in the present application.

. . .

The Examiner has referred to decisions of the Commissioner published in the C.P.O.R. on December 20, 1977 and on May 23, 1978 to support his contention that "treatment of animals is not patentable"...

In the decision of December 20, 1977 the ... summary ... reads ...

> . . .
>
> It was held that a product used to promote weight increase in animals is a "medicine" within the meaning of Section 41 of the Patent Act" (emphasis added)

In the May 23, 1978 decision the ... summary reads ...

> . . .
>
> A product used to promote weight increase in animals is a "medicine" within the meaning of Section 41 of the Patent Act." (Emphasis added)
>
> It is submitted that with the repeal of Section 41(1) these two decisions cannot be relied upon at this time. Furthermore, since the recent Goldenberg decision, the term "medicine" no longer includes some of the products listed in the definition of "medicine" in the ICI decision. Thus there is no reason why the term "medicine" should continue to be interpreted as any product given orally or by injection to an animal for purposes other than medical treatment.
>
> . . .

Subsequent to the response to the Final Action, the Applicant submitted amended claims 1 to 3, saying, in part, as follows:

> . . .
>
> New claims 1 to 3 are now directed to the use of selected cell lines for increasing milk production in cows (claims 1 and 3) and for increasing animal growth (claims 2 and 3). The new use claims are now permissible under the new Patent Office practice.

Following a telephone discussion between the Patent Agent and the Board, further amendments were made to claims 1 to 3 by letter dated April 5, 1990, in which the Agent argued, as follows, in part:

> . . .
>
> In a subsequent telephone discussion with the Acting Chairman of the Appeal Board, the latter felt that use Claims 1 and 2 should be directed to the use of the hollow fiber recited and characterized in claims 4 and 5. Applicant begs to disagree and does not believe that use claims should be restricted to the use of a hollow fiber as recited in claims 4 and 5 for the following reasons.
>
> It is submitted that two aspects of the present invention are now being claimed as follows:
>
> 1. The use of a cell line now recited in Claims 1 and 2 in their encapsulated form; and
>
> 2. A specific hollow fiber containing particular recombinant mouse cells (Claims 4 to 7).
>
> The first aspect of the present invention is clearly set out in page 1, lines 7 to 13 wherein the invention is stated as "the use of novel recombinant DNA molecules" while the second aspect is also given in page 1, lines 13-17 where it is indicated that the

> mouse cells can be encapsulated into hollow fibers. The two features are also set out clearly in the SUMMARY OF THE INVENTION in page 2.
>
> It is submitted that if use of encapsulated cell lines in Claims 1 and 2 were restricted to implantation by means of the hollow fiber recited in Claims 4 and 5, it would be an undue restriction and could deprive the applicant in the event that another party could implant the special cell lines by means other than the hollow fiber recited in Claims 4 and 5. Furthermore, hollow fibers containing an encapsulated cell line could very well not be the sole mode of implantation of encapsulated cell lines.
>
> Accordingly, due to the fact that the restricted cell lines recited in Claims 1 and 2 for the uses claimed are not anticipated, restricted claims to an encapsulated cell line for in vivo implantation in cows or animals should be allowed to provide the applicant with an adequate protection.
>
> . . .

The issue before the Board is whether or not the amended claims 1 to 3 contained in the letter dated April 5, 1990 overcome the rejection of claims 1 to 3 made in the Final Action for being directed to a medical treatment. Claims 1 to 3 submitted April 5, 1990 read:

> 1. The use of an encapsulated cell line selected from the group consisting of L-BHG-4-3, ATCC CRL-8537 and L-BGH-4-13, ATCC CRL-8536 for increasing milk in cows by in vivo implantation of said encapsulated cell line in said cows.
>
> 2. The use of an encapsulated cell line selected from the group consisting of L-BGH-4-3, ATCC CRL-8537 and L-BGH-4-13, ATCC CRL-8536 for increasing animal growth by implantation in vivo of said encapsulated cell line in said animal.
>
> 3. The use of an encapsulated cell line according to Claim 1 or 2, wherein said encapsulated cell line is implanted subcutaneously.

By the amendments made in response to the Final Action, the applicant presented claims to the use of selected cell lines in an effort to overcome the rejection that a method of medical treatment was being claimed. The Board regarded the amended claims as not completely defining the subject matter disclosed, and so informed the Agent who discussed the matter with the Applicant. By the amendments of April 5, 1990, claims 1 to 3 are directed to the use of the cell lines when encapsulated. The Agent reasoned the latter claims were not to a method of medical

treatment and should be acceptable. He pointed to the description on page 1, and argued that a hollow fiber "could very well not be the sole mode of implantation of encapsulated cell lines."

The Board considers that claims 1 to 3 submitted April 5,1990 are clear of the rejection made in the Final Action. The Board believes they are directed to subject matter which both finds support in the application and may form the basis of valid claims in view of the direction from Shell Oil v Commissioner of Patents, S.C.R. (1982) Vol. 11, p. 536. In the application before it, the Board thinks the structure of the carrier with the cell line is the combination that, as expressed in Shell, supra, "... is required in order to give effect to this particular use ...", and that provides "... the means for realizing on the newly discovered potential ..." described in the specifications. While it may well be that the arguments presented by the Agent are acceptable, the Board notes that the claims of April 5, 1990 were not before the Examiner when he took his Final Action.

The Board recommends, therefore, that the rejection of claims 1 to 3 for claiming a method of medical treatment be withdrawn, and that the application be returned to the Examiner for consideration of claims 1 to 3 submitted April 5, 1990, in light of the arguments presented by the Agent.

M.G. Brown
Acting Chairman
Patent Appeal Board

I concur with the findings and the recommendations of the Patent Appeal Board. Accordingly, I remand the application to the Examiner for continued prosecution.

J.H.A. Gariépy
Commissioner of Patents

dated at Hull, Quebec
this 13 day of August , 1990

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