Commissioner's Decision #1238
Décision du Commissaire #1238

TOPIC: F00; ;F20; OO
SUJET: F00; F20; OO

Application No: 616,544
Demande No: 616,544

C.D. 1238

COMMISSIONER'S DECISION SUMMARY

C.D. 1238 ....Application No. 616,544 (F00; F20; OO)

The claims of the application were rejected on the grounds of lack of invention under Section 2 of the Patent Act.

The application discloses polypeptides exhibiting erythropoietic activity and processes for their preparation by the methods of genetic engineering. Claims 1 to 4 of the application were rejected on the grounds that the subject matter disclosed was obvious in view of two cited references. The Board recommended that the rejection of the claims on the grounds of obviousness be reversed and that the application be returned to the examiner for further prosecution, a recommendation which was accepted by the Commissioner of Patents.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

The claims of patent application number 616,544 having been rejected under Subsection 45(2) of the Patent Rules, the Applicant asked that the Final Action of the Examiner be reviewed. The rejection has been considered by the Patent Appeal Board and by the Commissioner of Patents. The findings of the Board and the decision of the Commissioner are as follows:

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This decision deals with a request that the Commissioner of Patents review the Examiner's Final Action on patent application number 616,544 which was filed on October 22, 1992 as a divisional of patent application number 540,234 filed on June 22, 1987. The Applicant is The Board of Regents of the University of Washington, assignee of inventor Jerry S. Powell, and the invention is entitled "HUMAN ERYTHROPOIETIN GENE: HIGH LEVEL EXPRESSION IN STABLY TRANSFECTED MAMMALIAN CELLS@. The Examiner in charge issued a Final Action on November 28, 1995 refusing all of the claims in view of two cited references. The Applicant failed to reply to the Final Action by the due date but on May 28, 1997 applied for a reinstatement of the application which was granted. A supplementary response was made on September 8, 1997 requesting that the Examiner withdraw the rejection of the claims and the application was then referred to the Board for review.

The invention relates generally to the field of genetic engineering, particularly to the expression of glycoprotein products of recombinant genes, and more particularly to the expression of high levels of biologically active human erythropoietin from stably transfected cells. The claims of this divisional application are directed to a polypeptide exhibiting erythropoietic activity, said polypeptide being the expression product of a polynucleotide molecule comprising a human genomic DNA fragment which consists essentially of a nucleotide sequence corresponding to a 2.4 kb Apa I restriction fragment of a human erythropoietin gene or a sequence complementary thereto. Claim 1 which is representative of the rejected claims is as follows:

> 1. A polypeptide exhibiting erythropoietic activity, said polypeptide being the expression product of a polynucleotide molecule comprising a human genomic DNA fragment which consists essentially of a nucleotide sequence corresponding to a 2.4 kb Apa I restriction fragment of a human erythropoietin gene or a sequence complementary thereto.

In her Final Action the Examiner refused claims 1 to 4 in view of two references stating, in part, that:

> <u>References Reapplied</u>
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> | | | |
> |---|---|---|
> | Lee-Huang, S. | PNAS 81:2708-2712 | (May 1984) |
> | Jacobs, K., et. al. | Nature 313:806-810 | (Feb. 1985) |
>
> The claims of this application are rejected for lack of invention under Section 2 of the Patent Act as claiming old and known polypeptides.

> **Erythropoietin is old and well known in the art as demonstrated by Lee-Huang and Jacobs above.**
>
> **Said references not only demonstrate that the polypeptide is old but also that it has been cloned and successfully expressed recombinantly. In fact the DNA sequence disclosed and used by Jacobs differs from that of the instant application only by non-coding region. This would mean that the protein sequences resulting from recombinant expression would be identical. Applicant fails to demonstrate in the application as filed that the erythropoietin produced by the applicant differs in any way from that of the prior art. Applicant is again referred to the disclosure pages 10 (line 36 to page 11) and 11 (lines 17 to 22) where applicant specifically demonstrates that the polypeptide of the instant application has all of the expected properties of human erythropoietin.**
>
> **In their arguments of January 21, 1994, the applicant states that the method of using the ApaI DNA fragment, which is not demonstrated in the prior art, yields a different product, yet nowhere in the application as filed are the alleged differences demonstrated. As stated in the examiner=s last action, allegedly new methods of manufacture do not bestow patentability on old and known products. For guidance the examiner refers the applicant to Section 8.04 of The Manual of Patent Office Practice which states that an AApplicant is required to distinguish his new product from all other products by claiming it distinctly and explicitly...@. As described in the application as filed, applicant has failed to demonstrate that the allegedly new method of manufacture bestows any new properties upon the product, and has therefore failed to distinguish the product from that of the prior art.**

The questions before the Board are therefore whether or not the submissions made by the Applicant in its letter of January 21, 1994 should be considered and, if so, whether or not the polypeptide claimed in claims 1 to 4 is obvious in view of the cited prior art.

In issuing her Final Action the Examiner has taken the position that Applicant=s submissions of January 21, 1994 must be disregarded since, in the Examiner=s opinion, only the original disclosure can be considered. The disclosure appears to indicate that the polypeptide prepared by the Applicant is identical to the naturally occurring hormone erythropoietin and, on those grounds, the Examiner has rejected the present claims. In attempting to meet the Examiner=s objections the Applicant has submitted an analysis of the two cited references among other documents to show that the polypeptide claimed by the Applicant is in fact of a different chemical structure from naturally occurring erythropoietin.

Firstly in considering the Examiner=s Final Action the Board does not agree with the suggestion that Applicant=s submissions of January 21, 1994 relating to an analysis of the references and its submission of documents indicating that the polypeptide prepared by Applicant=s

process is novel should be disregarded. The Applicant is after all attempting to respond to the Examiner=s rejection of the claims as being directed to old and known products. The Board has therefore considered the material and argument submitted by the Applicant on January 21, 1994 and also the submission of September 8, 1997.

Secondly the Board, after reviewing the Applicant=s submissions, is satisfied that the polypeptide claimed by the Applicant is in fact novel and not rendered obvious by the references cited either alone or in combination.

The Board therefore considers that the rejection of the claims on the grounds of lack of invention for being directed to products old and well known in the art should be withdrawn.

In making this finding the Board has taken into account the judicial test for obviousness set forth in the Federal Court of Appeal decision in Beloit Canada Ltd. et al. v. Valmet Oy 8 C.P.R. (3d) 289, at page 294, namely:

> **The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right. The question to be asked is whether this mythical creature (the man in the Clapham omnibus of patent law) would, in the light of the state of the art and of common general knowledge as at the claimed date of invention, have come directly and without difficulty to the solution taught by the patent. It is a very difficult test to satisfy.**

The Board therefore recommends that the rejection of former claims 1 to 4 be withdrawn and that the application be returned to the Examiner for further prosecution consistent with the recommendation.

P.J. Davies **M. Howarth**

Chairman **Member**

I concur with the recommendation of the Board that the rejection of former claims 1 to 4 be withdrawn and that the application be returned to the Examiner for further prosecution consistent with the Board's recommendation.

A. McDonough
Acting Commissioner of Patents

Dated at Hull, Quebec,
this 11th day of May, 1999