Commissioner's Decision # 1276

Décision du Commissaire # 1276

TOPIC: B22

SUJET: B22

Application No.: 616,029

Demande no.: 616,029

COMMISSIONER'S DECISION SUMMARY

C.D. 1276 App'n 616,029

Obviousness

The Examiner rejected the application on the basis that some of the claims lacked support in the description of the application.

The Board agreed with the Examiner.

The Applicant was given three months in which to remove the rejected claims and to renumber the remaining claims. If the required amendments are not made within the three month time limit, the application will be refused.

IN THE CANADIAN PATENT OFFICE

DECISION OF THE COMMISSIONER OF PATENTS

Patent application number 616,029 having been rejected under Subsection 30(4) 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:

Agent for the Applicant

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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 616,029 entitled “IMMUNE RESPONSE TO TUMORS INDUCED BY ANTI-IDIOTYPIC ANTIBODIES”. Application number 616,029 is a divisional of patent application number 467,155, filed on November 6, 1984 and now abandoned. The Applicant is The Wistar Institute, assignee of inventors Hilary Koprowski, Dorothee Herlyn and Elaine DeFreitas.

A hearing before the Patent Appeal Board was held on October 1, 2003. The Applicant was represented by Mr. Edwin Gale and Dr. Trevor Mee of Kirby Eades Gale Baker. The Patent Office was represented by Dr. Linda Brewer, the examiner in charge of the application.

The invention relates to antibodies which are anti-idiotypic to antibodies that recognize tumor antigens, and their production and use in inducing an immunological response to tumors. The antibodies of the invention immunoreact with the paratopes of antibodies specific for solid tumor epitopes.

There are 13 claims in the application. Claim 1 is directed to an immortalized B lymphocyte that produces a monoclonal anti-idiotypic antibody. Claims 2 to 5 are directed to immortalized B lymphocytes and depend directly or indirectly on claim 1. Claims 6 to 10 are directed to monoclonal anti-idiotypic antibodies and depend on claims 1 to 5, respectively. Claim 11 is directed to a polyclonal antibody preparation. Claims 12 and 13 are directed to the use of a polyclonal antibody preparation and depend directly or indirectly on claim 11.

The Examiner issued a Final Action on February 28, 2002 in which claims 1 to 10 were rejected under Subsection 174(2) of the Patent Rules for lack of support in the description. Claims 11 to 13 were identified in the Final Action as being allowable.

Claims 1 and 6, representative of the claims rejected by the examiner, are as follows:

> 1. An immortalized B-lymphocyte that produces a monoclonal anti-idiotypic antibody which bears the internal image of an epitope present on a solid tumor cell, wherein said anti-idiotypic antibody
>
> (a) immunoreacts with paratope of a monoclonal antibody specific for said solid tumor cell epitope; and
>
> (b) will induce formation of anti-anti-idiotypic antibodies specific for said solid tumor cell epitope upon administration to a human.
>
> 6. The monoclonal anti-idiotypic antibody produced by the immortal B-lymphocyte of claim 1 substantially free of other antibodies.

In the Final Action, the Examiner stated, in part:

> Claims 1-10 still do not comply with Subsection 174(2) of the Patent Rules because there is no support in the present description for the subject matter of claims 1-10. The description does not specifically disclose "an immortalized B lymphocyte that produces a monoclonal anti-idiotypic antibody," as claimed in claim 1 and in dependent claims 2-5. The description does not specifically disclose a "monoclonal anti-idiotypic antibody produced by the immortal B lymphocyte" of claims 1-5, as claimed in claims 6-10.
>
> A Decision of the Commissioner of Patents concerning Canadian Patent 1,338,323, issued May 14, 1996, published in the Canadian Patent Reporter, Feb. 4, 1998, Vol 76 (3d), pages 206-218, determined that exemplary support was required for claims to hybridoma cell lines and monoclonal antibodies as novel products. Without specific description, claims to these products were not considered to be allowable. As Applicant has not disclosed any examples of novel anti-idiotypic (also referred to as anti-idiotype or anti-Id) antibodies, or of immortalized B lymphocytes or hybridomas producing monoclonal anti-Id antibodies, claims 1-10 are not allowable.
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> .....
>
> The present application resembles Canadian Patent 1,338,323 in that the present description does not show by specific example or state broadly that any lymphocyte producing the desired anti-Id antibody was immortalized, or that any immortalized B lymphocyte or hybridoma secreting an anti-Id monoclonal antibody, specific for a paratope of a monoclonal anti-tumor cell antibody, was actually produced. Further, there are no specific instructions given for the production of the claimed immortalized B lymphocyte and monoclonal anti-idiotypic antibody. Thus claims 1-10 fail to comply with Subsection 174(2) of the Patent Rules stands, because there is no support in the present description for the subject matter of claims 1-10.

In its response to the Final Action, the Applicant stated, in part:

> The Examiner has suggested that the present application lacks support for claims pertaining to monoclonal antibodies in accordance with the *Institut Pasteur* decision. The *Institut Pasteur* decision stated that the subject application lacked support for claims pertaining to monoclonal antibodies, since the disclosure "did not include any examples of monoclonal antibody production, and further 'did not include a clear reference or description to enable a person skilled in the art to make and use the invention without considerable and protracted experimentation".
>
> Whilst the present application does not specifically include examples of the production of monoclonal anti-idiotypic antibodies, clear teaching is provided to allow a person skilled in the art to generate such antibodies. This teaching includes two references on pages 15 and 16 of the description, to Kozbor et al. (1982) and Kozbor et al. (1983), which

> clearly demonstrate that the production of monoclonal antibodies involved well known and routine techniques at the claim date of the invention.
>
> Further teachings for monoclonal antibody production are provided on pages 7 and 8 of the application, which include details and references pertaining to the isolation of B lymphocytes from the spleen of a suitably immunized animal, subsequent immortalization of such B lymphocytes, and the isolation of monoclonal antibodies from the supernatant of substantially pure cultures of immortal B lymphocytes. The provision of such teachings therefore highlights the significant differences between the present application, and application that was the subject of the *Institut Pasteur* decision, which merely indicated that monoclonal antibodies were obtainable by "traditional techniques". Therefore, in contrast to the subject application for the *Institut Pasteur* decision, the present application provides a considerable quantity of details and references for the production and isolation of monoclonal antibodies, such that a person skilled in the art would have no difficulty and a clear indication of the most suitable, routine protocols for monoclonal antibody production.
>
> The *Institut Pasteur* decision does <u>not</u> state that claims pertaining to monoclonal antibodies are only allowable if an application specifically includes corresponding experimental data, and corresponding examples to provide support. Rather, the *Institut Pasteur* decision suggests that claims to monoclonal antibodies may be allowable in the absence of such experimental data, if the disclosure provides details of viable methods and techniques for monoclonal antibody production. The Applicant respectfully submits that the present application includes this necessary support by providing a clear indication of the intended methods for monoclonal antibody production by reference to Kozbor et al. (1982) and Kozbor et al. (1983), and well as the comprehensive teachings and references on pages 7 and 8 of the description.

Both the Examiner and the Applicant have referred to the Decision of the Commissioner of Patents concerning the application which issued as Canadian Patent No. 1,338,323 (hereinafter "Pasteur", published as *Institut Pasteur Application* 76 C.P.R. (3d) 206).

In "Pasteur", the Commissioner refused to grant a patent with claims to a hybridoma and a monoclonal antibody. The Decision reads in part:

> The Board cannot find any description of the hybridoma of claim 85 or any description of a method of preparing it provided in the above cited statements or in the entire description. No specific description of the monoclonal antibodies in claim 84 or a process for their preparation is disclosed. The only guidance as to the description of the monoclonal antibodies and the process by which they may be prepared is that they can be prepared by "traditional techniques".
>
> .....
>
> ... the Applicant does not show by examples or broad statements the steps that were successfully used to produce hybridomas secreting monoclonal antibodies which are capable of binding only with the specific antigen. Had any hybridoma and monoclonal antibody for certain antigens been prepared, then it would have been arguable that other hybridomas and monoclonal antibodies, which were claimed but unprepared or prepared but untested, could be allowable in view of the 'sound prediction' principle. In this case there is no consideration given by the disclosure to any monoclonal antibody so that there is nothing upon which to base a sound prediction. The Board finds that there is a lack of guidance in describing the core method to be used and the permissible modifications of that basic method for the specific antigens disclosed. Such deficiencies in guidance cannot be remedied by referring the person skilled in the art of (sic) experiment with the 'traditional techniques'.

The Examiner has argued that the instant application neither discloses monoclonal antibodies (no working examples) nor includes any specific instructions for their preparation and thus is similar to the "Pasteur" application. The Applicant agrees that there are no examples of monoclonal antibody preparation but contends that unlike in the "Pasteur" application, there is a "considerable quantity of details and references for the production and isolation of monoclonal antibodies, such that a person skilled in the art would have no difficulty and a clear indication of the most suitable, routine protocols for monoclonal antibody production" and that "Pasteur" "suggests that claims to monoclonal antibodies may be allowable in the absence of such experimental data, if the disclosure provides details of viable methods and techniques for monoclonal antibody production." According to the Applicant, the "details" of monoclonal preparation can be found on pages 7, 8, 15 and 16 in the specification.

On page 7, at lines 11 to 13, the Applicant discloses that "[m]onoclonal anti-idiotype antibodies substantially free of other antibodies can be isolated from the supernatant of substantially pure cultures of immortal B lymphocytes" and at lines 18 to 20, that "[t]he production of immortal B lymphocytes from normal B lymphocytes that produce anti-idiotype antibody is within the skill of the art." A number of references to the scientific literature are then listed. In the paragraph bridging pages 7 and 8, there is a short description of how human B

lymphocytes producing anti-idiotypic antibodies can be obtained. Page 15, at lines 13 to 33 and page 16, at lines 1 to 3, provide an overview of B lymphocyte immortalization and hybridoma production. Reference is made to two publications by Kozbor et al.

The Board can find no specific or detailed teaching of monoclonal antibody production in the cited passages. Rather, the Applicant has provided a very general description of how monoclonal antibodies "can be isolated". Instead of referring one to "traditional techniques" as in "Pasteur", the Applicant makes reference to two publications of Kozbor et al. which presumably is the core method to be used for making hybridomas. However, the Applicant has not disclosed a detailed description of this method or any permissible modifications, nor has the Applicant shown that it was successful in using the method to produce a hybridoma.

The Board is not satisfied that the Applicant has made an invention with respect to monoclonal anti-idiotypic antibodies or immortalized B-lymphocytes secreting these.

At the oral hearing and as part of its submission to the Board, the Applicant proposed an amendment to its application to replace page 2 of the description with new pages 2 and 2a and to add new claims 14 to 16. New pages 2 and 2a include an amendment to the "summary of the invention" to include the subject matter of new claims 14 to 16.

However, the Board has not considered the Applicant's proposed amendments. When the Applicant's response to a Final Action does not satisfy the Examiner that the reasons for rejecting the application have been overcome, the application is referred to the Patent Appeal Board. The Board is responsible for conducting a full and complete review of the prosecution of the application but the examination process does not continue with the Board. Once the time to respond to a Final Action has expired, an application may only be amended pursuant to Section 31 of the Patent Rules, which states

> An application that has been rejected by an examiner shall not be amended after the expiry of the time for responding to the examiner's requisition, made pursuant to subsection 30(4), except
> (a) where the rejection is withdrawn in accordance with subsection 30(5);
> (b) where the Commissioner is satisfied after review that the rejection is not justified and the applicant has been so informed;
> (c) where the Commissioner has informed the applicant that the amendment is necessary for compliance with the Act and these Rules; or
> (d) by order of the Federal Court or the Supreme Court of Canada.

In summary, the Board concludes that claims 1 to 10 do not comply with Subsection 174(2) of the Patent Rules and that the Examiner correctly rejected the claims. The Board recommends that the Commissioner:

1) inform the Applicant, in accordance with paragraph 31( c) of the Patent Rules, that the following amendment of the application is necessary for compliance with the Patent Act and Patent Rules: deletion of claims 1 to 10 and the renumbering of claims 11 to 13 as claims 1 to 3, respectively, with claim dependencies amended accordingly;

2) invite the Applicant to make the above amendment within three (3) months of the date of the Commissioner's decision; and

3) advise the Applicant that, if the above amendment is not made within the specified time, the Commissioner intends to refuse the application.

M. Gillen Chairman | M. Wilson Member | J. Cavar Member

I concur with the findings and recommendations of the Patent Appeal Board. Accordingly, I invite the Applicant to make the above amendment within three (3) months from the date of this decision, failing which I intend to refuse the application.

David Tobin

Commissioner of Patents

Dated at Gatineau, Quebec,

this 5th day of April, 2007