

**BEFORE CONTROLLER OF PATENTS
THE PATENT OFFICE, DELHI**

THE PATENTS ACT 1970
(Section 15)

In the matter of application No.4262/DELNP/2005
Dated 21st September 2005 filed by Medvet Science Pty
Ltd An Australian Company

Hearing held on 13th January 2009 at 02:30 P.M.

Present:

Ms. Archana Shanker ----- Attorney representing the applicant

Ms. Arpita Kulshrestha----- Agent representing the applicant

Dr.Jyoti Verma ----- Examiner of Patents & Designs

O R D E R

Medvet Science Pty Ltd, An Australian company of 38 Payneham road, Stepney, South Australia 5069, Australia through their patent attorneys M/S Anand & Anand filed a patent application No. 4262/DELNP/2005 on 21st September 2005 for their invention related to “A method of Diagnosis and Treatment” claiming a method for detecting an apoptotic cell in a subject or in a biological sample from said subject, said method comprising contacting cells or cell extracts from said subject or biological sample with an interactive molecule directed to a nuclear molecule or antigenic portion thereof and screening for interactive molecule-nuclear molecule complex formation wherein the non-nuclear localisation of said complex is indicative of an apoptotic cell. The applicants also claimed the priority date of Australian application No 2003900777 dated 21-02-2003 and 2003901126 dated 06-03-2003 and international application No PCT/AU2004/000223 Dated 23-02-2004.

2. On the receipt of request for examination on 03rd February 2006, this application was examined by the Patent Office and First Examination Report (FER) thereof was issued on 11th January 2008 vide this office letter No. 4262/DELNP/2005/8821. The examination report *inter-alia* contained the objections relating to lack of novelty and inventive step u/s 2(1)(j) of the Patents Act 1970 in view of citations cited in ISR and IPER as well as not patentable within the provisions of clause (d), (e) and (i) of Section 3 of Patents Act 1970 as amended in 2005.

3. The agents for the applicant responded to the objections contained in First Examination Report on 09th January 2009 and resubmitted the documents. In their submissions they stated that none of the documents cited in International Search Report or IPER teach or suggest a method for detecting an apoptotic cell in a subject or in a biological sample from said subject, said method comprising contacting cells or cell extracts from said subject or biological sample with an interactive molecule directed to a nuclear molecule or antigenic portion thereof and screening for interactive molecule-nuclear molecule complex formation wherein the non-nuclear localisation of said complex is indicative of an apoptotic cell and hence present application does not lack inventive step and novelty. Regarding the objection of section 3(i), they submitted that according to Sec 3(i) of Patent Act the provision is limited to treatment of human being/animals and is not directed to include analysis of biological sample. Treatment of body tissues or fluids after they have been removed from the human or animal body is not excluded from patentability in so far as these tissues or fluids are not returned to the same body. They also submitted that in **Joos v. Commissioner of Patent (1973) RPC 59**, court held that “treatment” in relevant senses means that the purpose of application of a process or substance to the body must be to arrest or cure of a disease or diseased condition or correcting some malfunction or amelioration of some incapacity or disability. Regarding the objection u/s 3 (d) and 3(e) the claims were deleted. The application was examined again considering the submissions filed by the agent and the case was discussed with the agent. But the examiner was not satisfied with the submissions as according to him the claimed method still fall with the parameters of treatment and hence not patentable under section 3(i) and also the applicant didn't provide any submissions w.r.t prior art which could support that the claimed invention is novel and involves inventive step and therefore a subsequent examination report was issued on 12th January 2009 which happens to be the last date to put the application in order for grant and accordingly the agents for the applicant requested for an opportunity to be heard before the controller under section 14 of Patents Act 2005. On their request a hearing was fixed on 13-01-09. The hearing was held as scheduled.
4. The agent in their written submission dated 13th January 2009 submitted that their invention is novel and involve inventive step over prior art. They also submitted that the present invention can be distinguished from the documents D1-D5 in as much that it was previously understood with anti nuclear antibody binding was not related to apoptosis induction i.e. dependent upon permeabilization of the cell that is surface membrane related and depended upon mechanism of binding other than the passive

entry and specific binding to antigen contained within the apoptotic body. They also submitted that none of the citations teaches or suggests the mechanism of detecting apoptotic cells perse using nuclear molecule-immunointeractive complex. The submissions regarding the objection of 3(i) were same as submitted earlier. In the amended set of claims, some claims were deleted and only 9 claims were retained which are on the record.

5. I have examined the submissions of the agent with respect to the prior art and claimed invention and of the opinion that the invention claimed involves the novelty and inventive step over the prior art. But, the claims still fall under the purview of 3(i) of Patent Act 2005. I have also examined the submissions of the agent with respect to the provisions of section 3(i) of the Patent Act 1970. In this connection I would like to quote these provisions herein.

3(i) Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products, is not patentable.

From the above provision it is very clear that any process of treatment including medicinal, surgical or diagnostic is not patentable. The applicants are claiming a method for detecting an apoptotic cell in a biological sample which provides an indication of a particular disease or condition or a propensity for development of a disease of conditions so that the conditions of a subject are monitored. The detection of apoptotic cell is done with the help of diagnostic agents such as immunointeractive molecules such as antibodies. This clearly indicates that claimed method of the alleged invention is nothing but a diagnostic method

Having considered all the facts, submission made by the agent for the applicant during the hearing and as well as all the documents on record and also in view of my above findings, I hereby refuse this application to proceed further for grant of patent as the claimed method is a diagnostic method which is not patentable u/s 3(i) under the provisions of the Patents Act 1970.

Dated, the 13th day of May, 2009.

(Dr. K.S. Kardam)

Deputy Controller of Patents & Designs

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