

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

THE PATENTS ACT 1970
(Section 15)

In the matter of application No.3498/DELNP/2005
Dated 08th August 2005 filed by Indena S.P.A
An Italian company

Hearing held on 27th January 2009 at 11:30 A.M.

Present:

1. Ms. Smita Sharma ---- --- Agent representing the applicant
2. Dr.Jyoti Verma ----- Examiner of Patents & Designs

O R D E R

Indena S.P.A, an Italian company, of Via Orteles, 12, I-20139 Milano, Italy through their patent attorneys M/S Kan & Krishme filed a patent application No. 3498/DELNP/2005 on 08th August 2005 for their invention related to “The use of Lupin Conglutin for the treatment of Type-II Diabetes”. The applicants have also claimed the priority date of Italy application No MI2003A000237 dated 11-02-2003 and international application No PCT/EP2004/001111 Dated 06-02-2004.

2. On the receipt of request for examination on 27th January 2006, the instant application was examined by the Patent Office and First Examination Report (FER) thereof was issued on 31st December 2007 vide this office letter No. 3498/DELNP/2005/8321. 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 as well as not patentable within the provisions of clause (e) of Section 3 of Patents Act 1970 as amended in 2005 and also the claims being not definitive.

3. The agents for the applicant responded to the objections contained in First Examination Report on 17th November 2008 and resubmitted the documents after amending the claims which were restricted to pharmaceutical composition. In their submissions they stated that their claims are novel over prior art as D1 discloses only increase of glucose-induced insulin release in vitro by water soluble substances of Lupin albus. They also submitted that D2-D4 do not disclose the pharmaceutical use of type II Diabetes of the compound claimed in present invention. Applicants submitted that their invention has inventive step over prior art as the extract of D1 is prepared by boiling of lupin seeds for two hours and the thermal shock causes protein denaturation, therefore the extract of D1 cannot contain active gamma conglutinin and hence the skilled person would not have ascribed the hypoglycaemic effect of D1 extracts to gamma conglutinin. They also supported that the present invention teaches to isolate gamma conglutinin through a process wherein temperature never raise beyond 40 degree Centigrade to avoid protein denaturation. No submission has given with respect to the documents D2-D4 regarding inventive step. Regarding the objection of section 3(e), again no submission was given the agent. 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 and the discussions as the applicant didn't provide the ratio of all the ingredients and the specification did not contain any comparative data with respect to prior art to support that the claimed invention is novel and involve inventive step. Accordingly the agents for the applicant requested for an opportunity to be heard under section 14 of Patents Act 2005 and therefore a hearing was fixed on 27th January 2009 at 11:30AM and matter was heard. The agents also gave written submissions at the time of hearing

4. The agent in their written submission dated 17th November 2008

reiterated the same arguments and submitted that their invention is novel and involve inventive step over prior art. In the amended set of claims filed on 17th November 2008, the claims were deleted and only 3 claims relating to pharmaceutical compositions were retained-.

5. I have gone through the description and claims of the specification as amended on 17th November, 2008. It has been known in the prior art given in the specification as well as disclosure in the D 1 document that lupin alkaloid lupanine is considered responsible for hypoglycaemic effect of lupin extract. It is also known that conglutin gamma and homologues protein also proved very powerful in reducing plasma curbs after glucose administration in the red. Further, applicant have also admitted in the specification that hypoglycaemic effect of lupin meal is also known and described on page 4 of the specification. However, the applicants claims that use of conglutin gamma for the treatment of type II diabetes has not been disclosed which is the invention of the applicant. Since the properties of lupin protein are known to be hypoglycaemic are well known in the documents as referred above, it appears that the applicants are trying to claim a mere use of known substances of which the properties are known. Moreover, the applicants have claimed a pharmaceuticals composition containing lupin conglutin gamma or lupin protein in certain quantity for instance 150 to 750 mg but there is no other ingredient disclosed in the alleged composition. In order to be a composition a product must disclose atleast two ingredients. I have gone through entire specification including examples but did not find any other second ingredients except certain excipient which are commonly used in the preparation of such pharmaceuticals composition for complementary activities. However, they have no role to play in the composition. Further, the applicants have also failed to provided any data comparing the effect of the alleged composition with respect to the prior art where the hypoglycaemic properties of lupin protein have already been disclosed. In view of this, I am of the opinion that the

alleged invention claiming the pharmaceutical composition of lupin conglutin gamma or lupin protein is lacking inventive step as well as being as composition due to non disclosure of other ingredients of the composition.

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 due to lack of inventive step and lack of description to support the composition in accordance with the provisions of the Patents Act 1970.

Dated, the 08th day of May, 2009.

(Dr. K.S. Kardam)
Deputy Controller of Patents & Designs

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