The Patents Act 1970
Section (15)

In the matter of the application for

Patent Application No.2090/KOLNP/2006 filed on 25/07/2006
(International Application No. PCT/US2005/001581, filed on 21/01/2005)

UNIVERSITY OF MIAMI …… Applicant.

Applicant's agent – M/S ANAND AND ANAND ADVOCATES, NEW DELHI

Hearing held on – 02/08/2013

Decision

The application was filed as national phase application of a PCT international application having the title of invention as "TOPICAL CO-ENZYME Q10 FORMULATIONS AND METHODS OF USE". The application was published on 18/05/2007 and Request for examination (F18) was filed on 18/01/2008. The application was examined and First Examination Report was issued on 05/05/2010.

On examination of the amended documents received after FER, it was found that the application was not put in order as per The Patent's Act, 1970 and many objections are pending for this application. As the last date was already over, the remaining objections were communicated to the agent through hearing letter and a hearing was held on 02/08/2013. There were eight (08) objections mentioned in the hearing letter. The major technical objections were on the ground of novelty / inventive step, section 3(d) and 3(e) of the 'Act.

The revised principal claim filed after hearing is as follows:

Claim 1. A pharmaceutical liposomal composition for the treatment of cancer comprising 0.01 % to 30 % w/w of Coenzyme Q 10 and a liposome formulated for tropical or intravenous administration.

Dr. Archana Shanker, attorney of the applicant proposed revised claims set during the hearing and strongly argued in favour of inclusion of post research technical results in support of enhancement of efficacy / synergism of the revised claimed composition (Coenzyme Q 10 and Liposome) as claimed in the principal revised claim submitted after hearing. I agree that the facts (along with huge supporting documents) as explained by Dr. Archana Shanker have been directed to illustrate the actual post-research scenario but in comparison to what disclosed in the complete specification, these further technical results or achievements become grossly substantive and effect of further research. Therefore, inclusion of those results in the descriptive part of the complete specification is not allowable as per section 59 of the 'Act.

Use of liposome as carrier of active drug molecules is already known in the art. Therefore, in many pharmaceutical compositions liposome has been found to be used as a carrier of drug molecule. The proposed revision of claim combining the carrier liposome with active drug molecule, Coenzyme Q 10 and evidence for enhancement of activity (as proposed by further documents) are beyond the scope of 'invention' as described in the complete specification as on record. Applicant did not incorporate the further experimental results in the specification by way of amendment within stipulated time period. At this stage, inclusion of major technical data and change of direction of the invention is not acceptable and merit of the invention has to be decided based on the disclosure as on record. As per present disclosure, specification lacks in technical data for enhancement of efficacy or synergism. Therefore, the 'invention' can not be acknowledged to involve inventive step [as per section 2(1)(j)] and also not patentable under section 3(d) of the 'Act.

Also, the revised claim as drafted falling indirectly u/s 3(i) [method of treatment] of the 'Act and thus, not allowable.

In view of the above, the revised claim set is not patentable and the application is hereby refused for grant of patent under section 15 of the 'Act.

Dated, 27th Feb., 2015

(Soumen Ghosh)
Asst. Controller of Patents & Designs.