

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

THE PATENTS ACT 1970  
(Section 15)

In the matter of application No.2145/DELNP/2004  
dated 23rd July 2004 filed by M/S AstraZeneca AB,  
a Swedish company

**Hearing held on 3<sup>rd</sup> September 2008**

Presents:

1. Shri Debashish Banerjee ---- --- Agent representing the applicant
2. Dr.Jyoti Verma ----- Examiner of Patents & Designs

**ORDER**

M/S AstraZeneca AB, a Swedish company, of S-151 85 Sodertalje, Sweden, through their patent attorneys M/S Remfry & Sagar filed a patent application No.2145/DELNP/2004 on 23<sup>rd</sup> July 2004 for their invention related to “a composition for inhalation” claiming a pharmaceutical composition comprising formoterol, budesonide, HFA 227, PVP and PEG characterised in that the PVP is present in an amount of 0.001%w/w and the PEG is present in an amount of 0.3% w/w”. The applicants have also claimed the priority date of Swedish application No 0200312-7 dated 01-02-2002 and international application No PCT/SE2003/000156 Dated 29-01-2003.

2. On the receipt of request for examination on 29<sup>th</sup> December 2005, this application was examined by the Patent Office and First Examination Report (FER) thereof was issued on 03<sup>rd</sup> Sep 2007 vide this office letter No. 2145/DELNP/2004/4673 dated 3<sup>rd</sup> September 2007. 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 US Patent 6004537 and EP0534731 as well as not patentable within the provisions of clause (e) 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 29<sup>th</sup> April 2008 and resubmitted the documents. In their submissions they stated that their claims are novel and inventive as prior art does not disclose or suggest a formulation with 0.001% PVP and 0.3% PEG. They also submitted that the inventive step is supported by a more stable formulation which is demonstrated by the test data in the specification. Regarding the objection of section 3(e), the agent amended the claims by giving the ratio of all ingredients in order to meet the requirement. The application was examined again considering the submissions filed by the agent. But the examiner was not satisfied with the submissions for inventive step and issued a subsequent examination report on 21<sup>st</sup> Aug 2008 with a further objection of providing comparative data with respect to prior art as the specification did not contain any comparative data which could support that the composition of present invention is having more suspension stability.

4. The agents for the applicant responded again on 01<sup>st</sup> Sep 2008 to the objections contained in subsequent examination report dated 12<sup>st</sup> August 2008. In their submissions, again stated that their invention is novel and inventive as the claimed compositions are more stable **with 0.001% PVP and 0.3% PEG and contended that test data and figure 3 and figure 7 also illustrate this aspect.** The application was examined again considering the submissions filed by the agent. However, the examiner was still not satisfied with the submissions particularly with respect to inventive step and novelty of the invention and matter was discussed in detail with the agent on 3<sup>rd</sup> September 2008 which happen to be the last date to put the application in order for grant. Therefore the agent requested for an opportunity to be heard before the controller under section 14 of Patents Act 2005. Accordingly a hearing was fixed on 03<sup>rd</sup> Sep 2008 itself at 5:30PM and matter was heard. However as requested by the agent they were allowed to file the written submissions by 9<sup>th</sup> September 2008 and same were submitted in time.

5. The agent in their written submission dated 9<sup>th</sup> September, 2008 stated that at the outset no requirement for said comparative data was raised in the First Examination Report and applicants was given only a few days to adduce additional comparative data which was not possible at such a short notice. The agent for the applicant once again reiterated that the claims are novel and inventive as the application provides ample evidence that formulations with 0.001% PVP give superior formulation. They further submitted that although 0.01%

PVP concentration also gives stable formulation 0.001% PVP concentration better over the whole range data. Therefore requested the controller to consider the whole package of data in the application which in the opinion of the applicants shows that 0.01 PVP is the prefer concentration. With regards to published US Patent 6004537 the agent submitted that this document relates to pharmaceuticals aerosol formulation containing budesonide and formoterol dissolved or solubilised in fluoroalkane and cosolvent. The formulation disclosed does not contain polyvinylpyrrolidone (PVP) and polyethylene glycole (PEG). It was further submitted that this document does not motivate a person skilled in the art to make formulation comprising PVP and PEG which will exhibit increased suspension stability. The claimed invention on the other hand discloses that hydrofluoroalkane (HFA) formulations comprising formoterol and budesonide together with PVP And PEG exhibit excellent physical suspension stability. The specification also provides test data which clearly demonstrate that formulation with 0.001% PVP and 0.3% PEG are particularly stable.

6. With regards to European No.EP0534731, the agent submitted that this document relates to a pressurised aerosol composition comprising a liquefied hydrofluoroalkane, a powdered medicament dispersable therein and a polymer soluble in the liquefied hydrofluoroalkane, wherein the polymer includes recurring structural units, the units being selected from amide containing units and carboxylic acid ester containing units. It was further stated that this document while discloses that polyvinylpyrrolidones having wide range of molecular weights gives acceptable suspension; it does not disclose a composition as claimed in the present invention. Therefore, it does not motivate a person skilled in the art to look at the very specific concentration of PVP with the expectation of the stable formulation. The range of concentration in claim 8 of this document is incredibly broad and skilled person does not get a clue of where to start. Therefore, in view of the above the claimed invention is novel and inventive over the cited document.

7. I have gone through the description in the specification particularly the data given on renumbered page 9 and 10 of the specification which reflects the degree of dispersion of suspension of the composition over time containing various percentage of PVP in the samples. In this table, the samples of 0.0001, 0.0005, 0.001, 0.01, 0.03 and 0.05 percent of PVP concentration are examined for their stability with respect to the time at various intervals. On perusal of this table, it can be seen that the PVP concentration of 0.01 also provides suspension

stability to the composition at various time intervals for various doses of budesonide. This therefore does not conclusively prove that the claimed composition is more stable at 0.001 concentration of PVP. With regard to comparative data with respect to the prior art, it may be noted that when the applicant is claiming a composition which is already in prior art he needs to show its efficacy with a comparative data while claiming the improved properties of a composition. In such situation it is imperative for the applicant to give such comparison in the specification itself rather than generating after issuing the examination report. Therefore the argument of the applicant that they were not given sufficient time to generate requisite data does not hold good.

8. On perusal of US 6004537 (Document A) which relates to the formulation containing budesonide, formoterol and at least one fluoroalkane and a cosolvent, it is observed that it does not contain stabilizing compounds such as PVP and PEG as present in the claimed invention and therefore the claimed invention appears to be novel. The document B (European publication No.EP0534731) relates to pressurised aerosol composition comprising a liquefied hydrofluoroalkane, a powdered medicament dispersable therein and a polymer soluble in the liquefied hydrofluoroalkane, wherein the polymer includes recurring structural units, the units being selected from amide containing units and carboxylic acid ester containing units. By comparing the claims contained in this document as well as the claims of the instant application it is observed the claimed invention in the instant application appears to be novel over this document as the ingredients in both the compositions are not same. However, the problem solved by the invention disclosed in this document is that of stabilisation of medicament composition by adding polymer wherein stabilising polymer (PVP) and a lubricant (PEG) are used in the composition of a pressurized aerosol container, in order to stabilise the composition. Further in claim 8 as well as in the description given in this document it has been stated that PVP is used at a concentration of 0.00001% to 10% w/w, more preferably at 0.001% to 5% w/w and especially at 0.001% to 1% w/w and PEG is used at a concentration of 0.01 to 4% w/w and preferably at 0.1% to 2% w/w. Therefore the submissions of the applicant that in the claimed invention the polymer (PVP) and lubricant (PEG) have been used in a much lower concentration i.e PVP as low as 0.001% and PEG as low as 0.3% do not hold good as such concentrations are within the range as mentioned in the prior art. Further, a person skilled in the art when facing the problem of stabilisation in the pharmaceutical

composition would realise that such a problem can be solved on the basis of information given in the document B of European published patent application by adding a stabilising polymer (PVP) and lubricant (PEG) on the basis of different K values of PVP and molecular weight of PEG disclosed in the said document. Hence in view of the disclosure in the document B (European publication No.EP0534731) the claimed invention lacks inventive step. Moreover, the applicants have also not given any comparative data with respect to the composition disclosed in the prior art as well as claimed invention to prove the enhanced suspension stability of the claimed composition.

Having considered all the facts, submission made by the agent for the applicant during the hearing 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 the patent due to lack of inventive step in accordance with the provisions of the Patents Act 1970.

Dated, the 6<sup>th</sup> day of February, 2009.

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

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