

EP1941899

Datum
Date 08.01.2015
Date

Blatt
Sheet 1
Feuille

Anmelde-Nr:
Application No: 06 798 469.0
Demande n°:

The examination is being carried out on the **following application documents**

Description, Pages

1-26 as published

Claims, Numbers

1, 2 received on 06-08-2014 with letter of 06-08-2014

1 Amendments (Art.123(2) EPC)

The present set of claims appears to fulfil the requirements of Art.123(2) EPC.

2 New Documents

The following documents are cited by the Examiner. A copy of the documents is annexed to the communication and the numbering will be adhered to in the rest of the procedure.

D8 R T Williamson ET AL: "The Treatment of Dibetes Mellitus with Casein and Cream",
British Med.J., 19 March 1915 (1915-03-19), pages 456-458,
XP055159599,
Retrieved from the Internet:
URL:http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2301930/pdf/brmedj07222-0004.pdf
[retrieved on 2014-12-19]

D9 VISSER J ET AL: "Short-term dietary adjustment with a hydrolyzed casein-based diet postpones diabetes development in the diabetes-prone BB rat",
METABOLISM, CLINICAL AND EXPERIMENTAL, W.B. SAUNDERS CO., PHILADELPHIA, PA, US,
vol. 52, no. 3, 1 March 2003 (2003-03-01), pages 333-337,
XP008097437,
ISSN: 0026-0495, DOI: 10.1053/META.2003.50052

2.1 D8 is a document dated as early as 1915 (!) disclosing the use of isolates casein in the treatment of Diabetes Mellitus.

2.2 D9 discloses the use of hydrolyzed casein in the treatment of Diabetes.

3 **Inventive Step (Art.56 EPC)**

3.1 Both documents are highly relevant for the assessment of inventiveness also taken into account the already cited documents from the Traditional Knowledge Database.

3.2 Even though the ED acknowledges that kappa-casein purified from milk for use in the treatment of diabetes as such has not been explicitly mentioned anywhere in the prior art, the skilled person was very well aware of the beneficial effects that casein treatment has on diabetes patients. This finding is not only based on the disclosure of documents from the Traditional Knowledge Database (for which sufficient evidence has been provided that those documents were indeed available before the priority date) but this is also supported by the newly cited documents that stand here exemplary as documents from medical literature that support the finding that casein treatment for Diabetes has a long history.

3.3 Now, as has been proven that casein treatment for Diabetes is known, the only difference that remains is the use of specific, purified kappa-casein. However, the present application is totally silent with regard to providing evidence that purified kappa-casein has any effect, if at all beneficiary, to diabetes treatment. The only effect that has been shown in the application is that kappa-casein has a GLP-1 promoting effect in one cell line. The ED does not acknowledge this one example to be sufficient to draw a line to the overall claim of treating Diabetes in general, see also previous objection under Art.84 that the therapeutic application is functionally defined by a mechanism of action which does not allow any practical application in the form of a defined, real treatment of a pathological condition (disease) (C-IV, 4.8). It follows from the above, taking into account the already cited documents and also new documents D8 and D9, the present set of amended claims lacks inventive step as required by Art.56 EPC. The skilled person was very well aware of the beneficial effects of casein treatment on Diabetes. The ED does not see where the skilled person could have encountered any technical problems in testing kappa-casein as a purified entity in said treatment, moreover, the application does not provide any evidence, that there had been any technical difficulties in purifying kappa-casein.

3.4 For the sake of procedural efficiency, the new documents are now sent to the Applicant in order to support the EDs opinion that there is not patentable subject matter in the application. In the next step, the Applicant will be invited to Oral proceedings.

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- 3.5 Applicant is again reminded, that, in order to avoid the costs associated with oral proceedings (Guidelines E-III, 4), the Applicant has the possibility to request a decision according to the state of the file (Guidelines E-X 4.4) open to appeal. The request should be submitted in written form and not contain any further amendments or arguments. If any further amendments or arguments are filed, oral proceedings will have to be held in case of the absence of the applicant.