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

Description, Pages

1-30 as originally filed

Claims, Numbers

1-6 filed in electronic form on 12-01-2010

Drawings, Sheets

1/4-4/4 as originally filed

1 After reconsideration of the present application, it is concluded that claim 1 lacks novelty (Article 52(1) and 54 EPC) for the following reasons.

1.1 Lactose is a native constituent of milk, skim milk, buttermilk, whey, butter and various further milk products.

1.2 Claim 1 does not specify any heating temperature and is therefore unclear (Article 84 EPC) in this regard. It is held that "heat" is fundamentally a relative term, except for a hypothetical temperature of absolute zero (= 0 K), and that heating may well involve temperatures such as 10 °C or 15 °C.

1.3 The mere existence of the above mentioned products thus invariably implies some extent of heating thereof, albeit not (necessarily) purposefully.

1.4 The presence of lactose in these products, in view of some degree of heating, implies a certain extent of lactosylation of the milk proteins, whether intended or not.

1.5 Irrespective of the preceding argument, it is self-evident that any milk product, such as the whey and milk disclosed in D1-D3 for instance, is subjected to storage at temperature above 0 °C at least for some time before processing and/or consumption, said storage inevitably involving heating in the presence of lactose.

1.6 D7 in particular discloses (cf. examples 1 & 2; §§ 0035-0038 & 0085; claims 1-3, 10 & 12) a method wherein ass's milk is heated at 30 °C for 1 hour, which step invariably gives rise to some degree of lactosylation of the milk proteins. The lactoserum having anti-inflammatory properties is to be used as

This problem has been solved by ~~providing specific fractions and/or preparation of milk which exhibit a COX-2 inhibiting activity, for treatment and/or prevention of diseases mediated by COX-2~~ the subject matter of claim 1.

In the figures,

Fig. 1 is a diagram showing the preparation of bovine milk fractions as outlined in Example 1.1.;

Fig. 2 is a diagram showing the preparation of human milk fractions as outlined in Example 1.2.;

pharmaceutical composition for treating e.g. chronic inflammation, bacterial, fungal or viral infections, or psoriasis, i.e. conditions falling within the scope of present claim 4.

1.7 The third party observations filed on 09-02-2012 under Article 115 EPC show that various milk products comprising both milk protein and lactose (e.g. buttermilk, human milk, milk) are known as being effective for treating e.g. cancer, arthritis, cough, fever etc. Whilst the presence of lactosylated proteins is not specifically disclosed in the submitted documents, it is apparent in view of the above explanations that said products contain at least minor amounts of such lactosylated proteins.

2 It appears that the present objections could be overcome by amending claim 1 such that the use is directly related to lactosylated milk protein fractions/ preparations, rather than to (undefined, as regards derivatisation) milk protein fractions/preparations, wherein milk proteins are lactosylated.

The applicant may wish to consider the following formulation: "use of one or more lactosylated milk protein fractions and/or one ore more lactosylated milk protein preparations exhibiting [...] wherein the lactosylated milk proteins are obtained by heating the milk proteins in the presence of lactose.".

3 The applicant is requested to file new claims which take account of the above comments.

3.1 The attention of the applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed (Article 123(2) EPC).

3.2 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based.

maintained in an anti- inflammatory factor producing state.

W003/006500 provides a method for obtaining a highly enriched TGF- beta protein fraction in activated form, from a liquid solution rich in proteins said to be soluble in the aqueous phase of milk and/or of whey, said method comprising the following steps: a) adjusting soluble proteins purified at a concentration between 5 to 30 g/litre of solution; b) precipitating part of the whey proteins by acid treatment of the solution thus obtained to a pH ranging between 4 and 5.5 and at a temperature ranging between 55°C and 68 °C ; c) carrying out a microfiltration of the treated solution by diafiltration, so as to obtain respectively a microfiltration retentate and a microfiltrate, d) reuperating the microfiltration retentate containing the protein fraction highly enriched in TGF- beta; e) drying the microfiltration retentate which has been subjected to diafiltration to obtain a powder highly enriched in TGF- beta.

EP-A-1151754 relates to the use of an equine milk fraction for the preparation of a composition having interleukin-1 (IL-1) production inhibiting activity.

WO 01/11990 discloses nutritional and pharmaceutical compositions with reduced threonine content. Said compositions may comprise as a main ingredient acid whey protein or sweet whey protein from which caseino-glyco-macropeptide has been removed. The removal of said casein protein is obtained by contacting sweet whey protein con- centrate with a cation exchange resin followed by treatment with an weakly anionic resin. A combination preparation directed to lowering the risk of diseases of civilization is described in DE 44 13 839. Said preparation comprises inter alia sweet whey protein, which is reported to interact with other constituents, magnesium, vitamin C, vitamin E, pro- vitamin A, vitamin B1and selenium, in order to provide the desired therapeutic effect.

Consequently, the problem of the present invention is to provide additional means for inhibiting cyclooxygenases, in particular COX-2, which means should be associated with a low risk of deleterious side effects.