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

Claims, Numbers

16-56	as published
1-15	filed with entry into the regional phase before the EPO

1 Art. 123(2) EPC:

Claim 1 is based on originally filed claims 1, 6, 8, 12 and 19 and on the description on page 20. The subject-matter of claim 20 is clearly and unambiguously derivable from the originally filed application.

The amended claims are allowable in accordance with Art. 123(2) EPC.

2 Prior art

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D3 WO 02/069993 A (FORSCH HISCIA VER FUER KREBSFO [CH]; WERNER MICHAEL [CH]; SCHALLER GER) 12 September 2002 (2002-09-12)

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.

D9 WO 2007/024496 A2 (SLGM MEDICAL RES INST [US]; MCDOWELL JR JOHN W [US]) 1 March 2007 (2007-03-01)

D10 M. M. Caffarel: " 9-Tetrahydrocannabinol Inhibits Cell Cycle Progression in Human Breast Cancer Cells through Cdc2 Regulation", Cancer research, vol. 66, no. 13, 1 July 2006 (2006-07-01), pages 6615-6621, XP55048739, ISSN: 0008-5472, DOI: 10.1158/0008-5472.CAN-05-4566

D11 PERNA F ET AL: "Cannabinoids induces apoptosis in human colon cancer cells via CB2 receptor activation", DIGESTIVE AND LIVER DISEASE, W.B. SAUNDERS, GB, vol. 38, 1 April 2006 (2006-04-01), pages S107-S108, XP025948651, ISSN: 1590-8658, DOI: 10.1016/S1590-8658(06)80287-2 [retrieved on 2006-04-01]

D12 LIGRESTI A ET AL: "Antitumor activity of plant cannabinoids with emphasis on the effect of cannabidiol on human breast carcinoma", JOURNAL OF PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, AMERICAN SOCIETY FOR PHARMACOLOGY AND EXPERIMENTAL THERAPEUTICS, US, vol. 318, no. 3, 1 January 2006 (2006-01-01), pages 1375-1387, XP002540820, ISSN: 0022-3565, DOI: 10.1124/JPET.106.105247

Document D3 discloses a cannabis extract comprising THC and CBD for treating cancer, inflammation and neurogenic pain.

Document D9 discloses the in vivo antitumor activity of cannabidiol and THC and cannabidiol- or THC-enriched cannabis extracts against the human breast carcinoma cell line MBA-MD-231 grafted in mice (see fig. 3).

Document D10 discloses compositions comprising cannabis for the treatment prostate cancer (see page 15).

Document D11 discloses that THC inhibits cell cycle progression and inhibits proliferation of human breast cancer cell lines (see page 6617).

Document D12 discloses that CB1 and CB2 agonists induce apoptosis in human colon cancer cells (see abstract).

3 The third-party observation received on 23.04.2010 pursuant to Art. 115 EPC; in particular document Exhibits 1-6 calls into question the patentability of the subject-matter claimed for the reasons given below. Thus, these documents will be taken into account in the proceedings (Guidelines E-V, 3).

These documents disclose formulations comprising Cannabis sativa for the treatment of cancer.

4 Novelty (Art. 54 EPC):

Claim1 lacks novelty in view of D9 for the following reasons:

D9 does not mention the TRPM8 antagonist activity of THC and cannabidiol, however this activity of THC and cannabidiol is only the explanation of a mechanism of action of a known therapeutic effect. Furthermore, it is considered that the feature "wherein TRPM8 activity is essential for the cancers survival" does not define a group of patients which is delimited from the patients of D9. Hence, claim 1 lacks novelty over D9. The dependent claims 2-5 and 11-15 as well lack novelty.

5 Inventive step (Art. 56 EPC):

Document D9 which is the closest prior art discloses the in vivo antitumor activity of cannabidiol and THC and cannabidiol- or THC-enriched cannabis extracts against the human breast carcinoma. Claims 6-10 differ in that the cannabinoids are THCA, CBDA, CBG, THCV or CBDV. The problem to be solved is defined as to provide alternative cannabinoids for the treatment of breast cancer. The application does not provide any evidence that these cannabinoids have the claimed therapeutic effect. Furthermore, the effect of the cannabinoids on the TRPM8 has not been shown for tumoral cells. There is no link between the receptor binding activity and the claimed therapeutic activity. The anti-tumoral activity of cannabinoids is known from D3 and D10-D12. The treatment of alternative cancer types is also rendered obvious by the disclosure of the prior art.

It is thus considered that claims 6-10 are not inventive.

6 The applicant is invited to file new claims which take account of the above comments.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).