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Datasheet for the decision of 22 October 2013

Case Number: T 0987/11 - 3.3.02

Application Number: 93909679.8

Publication Number: 656786

IPC: A61K36/00

Language of the proceedings: EN

Title of invention:
USE OF ISOFLAVONE PHYTO-OESTROGEN EXTRACTS OF SOY OR CLOVER

Patent Proprietor:
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Care for Women B.V.

Headword:
Isoflavones/ NOVOGEN

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - extension beyond the content of the application as filed (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

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Case Number: T 0987/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 22 October 2013

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 March 2011 concerning maintenance of the European Patent No. 656786 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 656 786, filed as application No. 93 909 679.8 based on international patent application PCT/AU1993/000230 published as WO 1993/023069, was granted with 11 claims.

Claim 1 as granted read as follows:

"The use of an isoflavone phyto-oestrogen extract of soy or clover, for the manufacture of a medicament for administration in unit dosage form for the treatment of pre-menstrual syndrome, symptoms associated with menopause, or prostate cancer."

II. Oppositions were filed against the granted patent under Article 100(a) EPC for lack of novelty and inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC for added subject-matter.

III. By its interlocutory decision under Article 106(2) and 101(3)(a) EPC, posted on 4 March 2011, the opposition division found that the patent met the requirements of the Convention with respect to the third auxiliary request.

However, neither the set of claims of the main request nor that of the second auxiliary request, the latter filed during oral proceedings, met the requirements of Article 123(2) EPC.

The subject-matter of the first auxiliary request was not inventive.

IV. The appellants (proprietor of the patent and opponents 03 and 06) lodged appeals against that decision. The appellant (patentee) filed five sets of claims as main and first to fourth auxiliary requests together with its grounds of appeal.

Opponents 03 and 06 withdrew their appeals before the date of the oral proceedings.

V. The appellant (patentee) with letter of 30 September 2013 filed a further set of claims as new main request and withdrew the third and fourth auxiliary requests. For the sake of clarity, the board deals with the new main request as main request and renumbers the remaining requests (former main, first and second auxiliary request) now first, second and third auxiliary requests. The (new) third auxiliary request is identical to the set of claims upheld by the opposition division and under the given circumstances is not to be considered because of the prohibition of *reformatio in peius*.

The wording of claim 1 of the main request is (differences with respect to claim 1 as granted marked by the board):

"The use of an isoflavone phyto-oestrogen extract of ~~soy or~~ red clover, wherein the isoflavone phyto-oestrogen extract comprises isoflavones selected from genistein, daidzein, biochanin A or formononetin, for the manufacture of a medicament for administration in unit dosage form which is a tablet or capsule for the treatment of ~~pre-menstrual syndrome,~~ symptoms associated with menopause~~, or prostate cancer~~."

Claim 1 of the first auxiliary request reads (differences with respect to claim 1 as granted marked by the board):

"The use of an isoflavone phyto-oestrogen extract of soy or red clover, wherein the isoflavone phyto-oestrogen extract comprises isoflavones selected from genistein, daidzein, biochanin A or formononetin, for the manufacture of a medicament for administration in unit dosage form which is a tablet or capsule for the treatment of pre-menstrual syndrome or symptoms associated with menopause~~, or prostate cancer~~."

The text of claim 1 of the second auxiliary request is (differences with respect to claim 1 as granted marked by the board):

"The use of an isoflavone phyto-oestrogen extract of soy or red clover, wherein the isoflavone phyto-oestrogen extract comprises isoflavones selected from genistein, daidzein, biochanin A or formononetin, for the manufacture of a medicament for administration in unit dosage form which is a tablet or capsule for the treatment of pre-menstrual syndrome or symptoms associated with menopause~~, or prostate cancer,~~ and wherein, in the case of an isoflavone phyto-oestrogen extract of soy, said medicament is for administration of isoflavone phyto-oestrogens in an amount from about 20 mg to 200 mg per day, optionally where the amount is 50 mg to 150 mg."

The wording of claim 1 of the third auxiliary request, maintained by the opposition division, is (differences with respect to claim 1 as granted marked by the board):

"The use of an isoflavone phyto-oestrogen extract of soy or red clover, wherein the isoflavone phyto-oestrogen extract comprises isoflavones selected from genistein, daidzein, biochanin A or formononetin, for the manufacture of a medicament for administration in unit dosage form which is a tablet or capsule for administration of isoflavone phyto-oestrogens in an amount from about 20 mg to 200 mg per day, optionally where the amount is 50 mg to 150 mg, for the treatment of pre-menstrual syndrome or symptoms associated with menopause~~, or prostate cancer~~."

VI. Opponent 06 maintained its objections concerning Articles 83, 54 and 56 EPC in general and opponent 03 objected under Articles 123(2), 83, 84, 54 and 56 EPC to the sets of claims filed with the appellant (patentee)'s grounds of appeal.

In particular, opponent 03 argued that there was no basis in the application as originally filed for the feature "for administration in unit dosage form" in claim 1 of the first auxiliary request (at that time still main request). Originally "unit dosage form" referred to a "health supplement" and not to the use of an extract for the manufacture of a medicament for the treatment of ..., and, additionally, as such it was linked to "wherein said phyto-oestrogen is present in an amount of from about 20 mg to 200 mg per dosage unit".

VII. In its submission of 30 September 2013, the appellant (patentee) did not reply to opponent 03's objections relating to its requests set out in the grounds of appeal.

VIII. On 22 October 2013, oral proceedings took place before the board in the absence of the representatives of all parties; duly summoned, the appellant (patentee) and most of the respondents had informed the board in advance that they did not wish to attend the hearings, while the rest of the respondents did not submit any notice.

IX. The appellant (patentee) requested in writing that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims filed as main request with letter of 30 September 2013 or on the basis of one of the sets of claims of the first to third auxiliary requests, all filed with the grounds of appeal.

Opponents 03 and 06 had requested in writing that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of the claim requests

2.1 The current requests

2.1.1 The amended claims filed by the appellant (patentee) as (former) main and first auxiliary request (now, and in the following text of this decision first and second auxiliary request) were already contained in its

statement of grounds of appeal and have to be regarded as a response to the arguments of the opposition division set out in its decision. Moreover, the subject-matter of the first and second auxiliary requests has already been discussed (in writing) during the appeal proceedings.

2.1.2 The subject-matter of the third auxiliary request is identical to the subject-matter as maintained by the opposition division. Since the appellants (opponents 03 and 06) have withdrawn their appeals, this subject-matter will not be ruled on in this decision, in accordance with the principle of no *reformatio in peius*.

2.1.3 The amended claims filed by the appellant (patentee) as (new) main request with letter of 30 September 2013 only contain the restrictions to red clover and to the treatment of symptoms associated with menopause. They are seen as a *bona fide* attempt to present a request which can be dealt with more easily.

2.2 Thus, there is no need for new, complex considerations.

2.3 In view of all these particular circumstances, the board uses its discretion under Articles 12(4) and 13 RPBA and admits the amended claims of the (new) main and first to third auxiliary requests into the proceedings.

3. Claim 1 of the main request refers *inter alia* to the
- use of an extract of red clover
- for the manufacture of a medicament
- for administration in unit dosage form.

Originally, "unit dosage form" is only disclosed in **product** claim 7, which reads "The supplement according to claim 1 in unit dosage form, wherein said phyto-oestrogen is present in an amount of from about 20 mg to 200 mg per dosage unit" and in claim 8 "... where the amount is 50 to 150 mg". **Method** claims 10 to 20 do not refer to a unit dosage, and nor does the description expressly disclose "**administration**" in terms of a method in the form of a use "in unit dosage form". Nor is there a link connecting the claimed product (supplement) to the methods.

The quantity of active substance present in a unit dosage form as the "unit dose" and the quantity to be administered are different things and independent of each other. So the unit dose in a medicament may for instance be 50 mg and the dose to be administered nevertheless 100 or 150 mg, meaning two or three unit doses.

Since, under these circumstances, the second-medical-use-type claims must be derived from the methods set out in the application as filed, but the disclosed methods do not provide for a sufficient basis, the board concludes that a "use of the isoflavones for the manufacture of a medicament for administration in unit dosage form" is not disclosed at all.

Consequently, the subject-matter of claim 1 of the main request is not disclosed in the application as originally filed, and claim 1 of the main request contains subject-matter that extends beyond the content of the application as filed.

4. First and second auxiliary request

4.1 The relevant features of the first auxiliary request are the same as those of the main request, and therefore its subject-matter fails to comply with Article 123(2) EPC for the same reasons.

4.2 In the second auxiliary request, the use of extract of red clover is unchanged compared to the main request. Therefore, the same arguments concerning added subject-matter apply to it *mutatis mutandis*.

5. Accordingly, claim 1 of neither the main request nor of both the first and second auxiliary requests fulfils the provisions of Article 123(2) EPC. The third auxiliary request is not an issue of this decision because of the principle of prohibition of *reformatio in peius*.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated