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Datasheet for the decision of 28 August 2020

Case Number: T 0639/19 - 3.3.01

Application Number: 10717084.7

Publication Number: 2419108

IPC: A61K31/56, A61K31/57, A61K9/20, A61K9/06

Language of the proceedings: EN

Title of invention:
METHOD FOR ON-DEMAND CONTRACEPTION

Patent Proprietor:
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The United States of America, as represented by The Secretary, Department of Health and Human Services

Opponents:
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Helm AG
Stada-Arzneimittel Aktiengesellschaft
HEXAL PHARMA AG
Generics (U.K.) Limited
EGIS Gyógyszergyár Zártkörüen Müködö Részvénytársaság
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Headword:
Ulipristal acetate contraception/HRA

Relevant legal provisions:
EPC Art. 100(c), 123(2)
EPC R. 103

Keyword:
Amendments - added subject-matter (yes) - all requests
Reimbursement of appeal fee - (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0639/19 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 28 August 2020

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 22 January 2019 revoking European patent No. 2419108 pursuant to Article 101(2) and 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Lindner
Members: J. Molina de Alba
B. Müller

Summary of Facts and Submissions

I. This appeal by the patent proprietors lies from the opposition division's decision revoking European patent No. 2 419 108.

The decision was based on the patent as granted (main request) and the claims of four auxiliary requests.

II. The patent had been granted with six claims. Claim 1 as granted reads as follows.

"*1. A method for contraception comprising orally administering a woman with an immediate-release form comprising ulipristal acetate or a metabolite thereof at an amount of 30 mg, within 120 hours after an intercourse*."

III. Seven oppositions were filed against the patent on the grounds of Articles 100(c), 100(b) and 100(a) EPC, the latter for lack of novelty and inventive step and for not being industrially applicable.

In the decision under appeal, the opposition division concluded *inter alia* that claim 1 as granted added subject-matter because it resulted from a combination of features selected from multiple lists in the application as filed. For the same reason, claim 1 of auxiliary requests I and IV added subject-matter too. Auxiliary requests II and III were not admitted into the opposition proceedings.

IV. The patent proprietors (appellants) filed an appeal against this decision.

With the statement of grounds of appeal, the appellants filed four sets of claims as auxiliary requests I to IV. Auxiliary request I is identical to auxiliary request I on which the decision under appeal is based. Auxiliary requests II-IV are new.

Claim 1 of auxiliary request I reads as follows.

"*1. A method for on demand contraception comprising orally administering a woman with a unit dosage of immediate-release formulation comprising ulipristal acetate or a metabolite thereof at an amount of 30 mg, within 120 hours after an intercourse.*"

Claim 1 of auxiliary request II derives from claim 1 of auxiliary request I but with the option "*or a metabolite thereof*" deleted.

Claim 1 of auxiliary request III derives from claim 1 of auxiliary request II but with the feature "*on demand*" also deleted.

Claim 1 of auxiliary request IV reads as follows.

"*1. A method for contraception comprising orally administering a woman with an immediate-release form comprising ulipristal acetate at an amount of 30 mg, within 120 hours after an intercourse, said immediate-release form being a compressed tablet.*"

V. Opponents 2 to 5 (respondents 2 to 5, respectively) replied to the statement of grounds of appeal. In its reply, respondent 2 requested the acceleration of the appeal proceedings.

Opponents 1, 6 and 7 (respondents 1, 6 and 7, respectively) neither replied to the statement of grounds of appeal nor made any request during these appeal proceedings.

VI. With a communication dated 23 January 2020, the board informed the parties that respondent 2's request for acceleration of the proceedings had been granted. The parties were summoned for oral proceedings to be held on 1 October 2020.

Subsequently, in a communication sent in preparation for the oral proceedings dated 30 April 2020, the board gave its preliminary opinion that all the requests on file added subject-matter.

VII. With a letter dated and received on 30 July 2020, the appellants announced that they would not be present at the oral proceedings and requested that a decision on the appeal be taken on the basis of their written submissions.

At the board's request (see the note about the telephone conversation dated 5 August 2020), the appellants confirmed their knowledge of the board's preliminary opinion and explicitly withdrew their request for oral proceedings.

VIII. The board cancelled the oral proceedings.

IX. The appellants' arguments, where relevant to the present decision, may be summarised as follows.

Claim 1 of each of the requests is not the result of arbitrary selections from multiple lists in the application as filed.

A method of contraception comprising administering ulipristal acetate or a metabolite thereof to a woman within 120 hours after intercourse finds literal support on page 2, lines 28-32 and page 3, lines 13-17 of the application as filed. In particular, administration within 120 hours after intercourse is one of the three equally preferred administration times disclosed in the application as filed. Each of the three administration times may be combined with the features subsequently disclosed on pages 4-9.

One of the features that may be combined with administration within 120 hours after intercourse is the preferred dosage of 30 mg. The preference for this specific dosage is apparent from the passage on page 9, lines 21-24, and from the fact that it is the sole dosage tested in the example in the application.

X. The respondents' arguments, where relevant to the present decision, may be summarised as follows.

Claim 1 as granted results from multiple selections within the disclosure of the application as filed.

The application discloses three administration times:

- within 72 hours before intercourse,
- within 120 hours after intercourse, and
- within 72 hours before intercourse and within 120 hours after intercourse.

These three embodiments are not disclosed at the same level of preference. Administration within 72 hours before intercourse is highlighted as preferred (page 2, lines 21-26), while administration within 120 hours

after intercourse is only disclosed as a general embodiment, i.e. without preference (page 2, lines 28-32). Moreover the application teaches administration within 72 hours before intercourse and within 120 hours after intercourse for optimal efficiency (page 10, lines 13-17). Hence, administration within 120 hours after intercourse is the least preferred of the three time windows.

With respect to the dosage of the active ingredient, the application discloses two equivalent alternatives, namely 30 mg and 20 mg (page 9, lines 21-26), so the choice of 30 mg constitutes a selection. The example in the application cannot support the view that the 30-mg dosage is generally preferred because it merely illustrates a specific embodiment where the active ingredient is administered twice within the menstrual cycle (page 10, lines 24-25).

XI. The parties' requests made during the written proceedings and relevant for this decision are the following.

- The appellants requested that the decision be set aside and that the patent be maintained as granted or, alternatively, that it be maintained in amended form on the basis of any of the sets of claims filed with the statement of grounds of appeal as auxiliary requests I to IV.

- Respondents 2 to 5 requested that the appeal be dismissed. In addition, respondents 2, 4 and 5 requested that auxiliary requests II to IV not be admitted into the appeal proceedings.

- Respondents 1, 6 and 7 did not file any request.

Reasons for the Decision

1. The appeal is admissible. It complies with the requirements pursuant to Articles 106 to 108 and Rule 99(2) EPC.

2. Main request (patent as granted) - added subject-matter

2.1 On the issue of added subject-matter in relation to the main request, the parties disputed whether the specific combination of features in claim 1 resulted from five different selections within the content of the application as filed, namely:

- mode of administration (oral),
- formulation (immediate-release form),
- active ingredient (ulipristal acetate or a metabolite thereof),
- dose (30 mg), and
- administration time (within 120 hours after intercourse).

In the board's view, at least the combination of a 30-mg dose with an administration time of within 120 hours after intercourse results from a selection from two lists that was not directly and unambiguously disclosed in the application as filed.

2.2 It was common ground among the parties that the application as filed discloses (page 2, lines 21-26; page 2, lines 28-32; page 3, lines 12-17; section

"Regimen" on pages 9-10) three different administration times for the active ingredient of claim 1, namely:

- within 72 hours before intercourse,
- within 120 hours after intercourse, and
- within 72 hours before intercourse and within 120 hours after intercourse.

The parties disputed whether the embodiment "within 120 hours after an intercourse" was equally preferred (appellants) or less preferred than the other two (respondents). The board holds that, irrespective of the level of preference of the embodiment, selecting it constituted at best (i.e. if equally preferred) a selection from a list of three elements.

2.3 Regarding the active ingredient dosage, the application discloses (page 9, lines 21-24) two equally preferred embodiments, namely 20 mg and 30 mg.

The appellants argued that the skilled person would have construed the 30-mg dosage as being preferred because the only example in the application discloses a 30-mg dose.

The board disagrees. As noted by the respondents, the example in the application discloses tests in which the active ingredient was always administered after intercourse, in an amount of 30 mg, twice during the menstrual cycle (page 10, lines 24-25). This restricted teaching could not provide sufficient basis for the skilled person to conclude that a 30-mg dose was generally preferred. This becomes apparent from the passages on page 6, lines 12-17 and page 10, lines 10-11 of the application as filed, which teach that administration is repeated at least twice a month,

preferably three times a month or once a week. Hence, the skilled person would not have concluded from the example that a 30-mg dose was necessarily preferred when the active ingredient was administered more frequently than twice a month (i.e. more frequently than twice within a menstrual cycle), e.g. three times a month or once a week.

Hence, the board concurs with the respondents that the choice of a 30-mg dose constitutes a selection out of two equally preferred alternatives.

2.4 Having regard to the above, the method of claim 1 contains at least a selection from two lists (administration time and dose) which was not directly and unambiguously disclosed in the application as filed. Therefore, claim 1 as granted adds subject-matter within the meaning of Article 123(2) EPC, so the ground for opposition under Article 100(c) EPC prejudices the maintenance of the patent as granted according to the main request.

3. Auxiliary requests I to IV - added subject-matter

Claim 1 of each of the auxiliary requests also contains a combination of the features "within 120 hours after an intercourse" and "30 mg" and is not restricted to an embodiment where the active ingredient is administered twice during the menstrual cycle. Thus, at least for the reasons explained in relation to claim 1 as granted, claim 1 of each of auxiliary requests I to IV is also contrary to Article 123(2) EPC.

4. In view of the outcome of the assessment of added subject-matter in relation to auxiliary requests II to IV, the board does not need to decide on the

respondents' request that those claim requests be held inadmissible pursuant to Article 12(4) RPBA 2007 (see also Article 25(2) RPBA 2020).

5. Reimbursement of the appeal fee

Under Rule 103(4)(c) EPC, the appeal fee is to be reimbursed at 25% if any request for oral proceedings is withdrawn within one month of notification of the communication issued by the board of appeal in preparation for the oral proceedings, and no oral proceedings take place.

The appellants' withdrawal of the request for oral proceedings was filed on 30 July 2020, i.e. more than one month after notification of the board's communication in preparation for the oral proceedings, which was posted on 30 April 2020. Hence, the appellants are not entitled to a reimbursement of the appeal fee pursuant to Rule 103(4)(c) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated