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Datasheet for the decision of 17 July 2007

Case Number: T 1063/04 - 3.3.02

Application Number: 98850109.4

Publication Number: 0911029

IPC: A61 31/565

Language of the proceedings: EN

Title of invention:
Ultra low dose oral conceptives with less menstrual bleeding and sustained efficacy

Patentee:
Duramed Pharmaceuticals, Inc.

Opponent:
Akzo Nobel N.V.
Bayer Schering Pharma Aktiengesellschaft

Headword:
Method of oral contraception/DURAMED PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
"Fifth and sixth auxiliary requests: admissibility (no)"
"Main request and First to Fourth auxiliary requests: added matter (yes), undisclosed combination of features"

Decisions cited:
-

Catchword:
-

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Case Number: T 1063/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 July 2007

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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 1 July 2004 revoking European Patent No. 0911029 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent No. 0 911 029, based on application No. 98 850 109.4, was granted on the basis of ten claims.

Independent claim 1 as granted read as follows:

"1. A method of human female contraception which comprises monophasicly administering a combination of estrogen and progestin for 60-110 consecutive days in which the daily amounts of estrogen and progestin are equivalent to 5-35 mcg of ethinyl estradiol and 0.025 to 10 mg of norethindrone acetate, respectively, following by non-administration for a period of 3-10 days."

II. Oppositions were filed against the granted patent by opponents 1 and 2. The patent was opposed under Article 100(a) EPC for lack of novelty and inventive step and under Article 100(b) EPC for insufficiency of disclosure.

III. The appeal lies from a decision of the opposition division revoking the patent under Article 102(1) and (3) EPC.

The decision was based on the main request, auxiliary request 1 and auxiliary request 2 all filed during the oral proceedings before the opposition division.

The opposition division considered that the subject-matter claimed in the main request complied with the requirements of Articles 123(2)(3), 84, 83 and 54(1)(2)

EPC, but that it lacked an inventive step in view of the teaching of one of the cited prior art documents.

Concerning auxiliary requests 1 and 2, the opposition division also regarded the subject-matter claimed as lacking an inventive step.

IV. The appellant (patentee) lodged an appeal against this decision, and filed seven requests with the grounds of appeal.

V. In the communication accompanying the summons to oral proceedings, the board inter alia expressed doubts as to whether the subject-matter of the requests on file were in conformity with the requirements of Article 123(2) EPC.

VI. With the subsequent letter of 15 June 2007, the appellant filed a main request and auxiliary requests 1-4 to replace all previously filed requests, as well as additional documents.

Claim 1 of the main request read as follows:

"1. A method of human female contraception which comprises orally monophasicly administering **tablets** comprising a combination of estrogen and progestin for **84** consecutive days in which the daily amounts of estrogen and progestin are equivalent to 30 mcg of ethinyl estradiol and 0.25 to 1.5 mg of norethindrone acetate, respectively, followed by administration of a **placebo** for a period of **7** days, wherein the combination of estrogen and progestin and the placebo are contained in a kit" (emphasis added).

Claim 1 of the first auxiliary request differed from claim 1 of the main request in that the feature "wherein the combination of estrogen and progestin and the placebo are contained in a kit" had been deleted.

Claim 1 of the second auxiliary request differed from claim 1 of the first auxiliary request in that the daily amounts of estrogen and progestin were amended to be "equivalent to 5-35 mcg of ethinyl estradiol and 0.025 to 10 mg of norethindrone acetate, respectively".

Claim 1 of the third auxiliary request read as follows:

"1. A method of human female contraception which comprises orally monophasicly administering **tablets** comprising a combination of estrogen and progestin for **80 to 110** consecutive days in which the daily amounts of estrogen and progestin are equivalent to 5 to 35 mcg of ethinyl estradiol and 0.025 to 10 mg of norethindrone acetate, respectively, followed by administration of a **placebo** for a period of **5 to 8** days" (emphasis added).

Claim 1 of the fourth auxiliary request differed from claim 1 of the third auxiliary request in that the daily amounts of estrogen and progestin were amended to be "equivalent to 20 mcg of ethinyl estradiol and 0.25 to 1.5 mg of norethindrone acetate, respectively".

VII. Oral proceedings were held before the board on 17 July 2007.

VIII. During oral proceedings, the appellant filed two further auxiliary requests as auxiliary requests 5 and 6.

Auxiliary request 5 differed from the main request filed with the letter of 15 June 2007 in that "followed by administration of a placebo" in claim 1 had been replaced by "followed by non-administration, said non-administration comprising administration of a placebo".

Auxiliary request 6 differed from the auxiliary request 4 filed with the letter of 15 June 2007 in that "followed by administration of a placebo" in claim 1 had been replaced by "followed by non-administration".

IX. The appellant's arguments, insofar as they are relevant to the present decision, can be summarised as follows:

With respect to the issues of admissibility of its requests filed during oral proceedings, the appellant argued that these were a direct response to objections raised for the first time during oral proceedings before the board by respondent opponent 2 with respect to Article 123(3) EPC. Moreover, the appellant contended that the subject-matter claimed did not represent a change in direction with respect to that of the requests already on file.

Regarding the requirements of Article 123(2) EPC, the appellant generally argued that it is well established in the case law that different parts of an application may be combined without necessarily giving rise to an objection of added subject-matter, in such cases where the passages concerned would be understood by the

skilled reader to be generally applicable to the claimed invention as a whole, and where the combination of features did not give rise to something that was in its own right both novel and inventive over the disclosure in the original application.

Concerning the requirement introduced into claims 1 of the main request and auxiliary requests 1 and 2 of **oral administration of tablets comprising a combination of estrogen and progestin for 84 consecutive days followed by administration of a placebo for 7 days**, the appellant argued that this limitation did not give rise to added subject-matter with respect to the application as originally filed.

The appellant indicated that the basis for the requirement for oral administration was to be found on page 7, line 19 of the application as originally filed.

The appellant further submitted that the section on page 8, lines 14-26 of the application as originally filed disclosed the types of administration regimens generally contemplated by the claimed invention.

The appellant argued that the reference in said section to "an administration free interval" (page 8, line 19) would be understood by the skilled person as meaning an interval free from administration of contraceptive active, which, as was evident from the disclosure of the application as originally filed, included pill-free days (page 8, lines 23-26) and the administration of a placebo (page 11, lines 11-14), i.e. an inactive pill.

The appellant further pointed to the final sentence on page 8 which disclosed, by way of example only, an 84/7 dosing regimen, with 7 pill-free days.

The appellant argued that the skilled person would read the above-mentioned section on page 8, lines 14-26 in combination with page 11, lines 7-14, which described very generally the provision of kits containing contraceptive active and placebo and would understand that the 84/7 dosing regimen mentioned on page 8, lines 23-26 was not inextricably linked to a pill-free interval and was therefore applicable to the embodiment in which a placebo is used, particularly in view of the reference to 84 tablets on page 11, line 9.

In addition, the appellant noted that further reference was made to the 84/7 dosing regimen in Example 1 (page 12, lines 21-22 and page 14, lines 7-9).

Thus, in the appellant's opinion, the combination of administration of 84 consecutive days of the contraceptive active followed by administration of a placebo for 7 days did not generate any new information with respect to the application as originally filed.

Concerning the requirement introduced into claims 1 of auxiliary requests 3 and 4 of **oral administration of tablets comprising a combination of estrogen and progestin for 80 to 110 consecutive days followed by administration of a placebo for 5 to 8 days**, the appellant similarly argued that the basis for this limitation could be found on page 11, lines 11-14 in combination with page 8, lines 14-26 of the application as originally filed.

The appellant referred to page 11, lines 11-14 as disclosing a preferred embodiment involving the administration of the contraceptive active in tablet form for at least 60 days followed by at least 3 days with placebo.

The appellant argued that the skilled person would understand the general dosage regimens disclosed on page 8, lines 14-26 to be applicable to said embodiment on page 11, lines 11-14.

Turning to this section on page 8, lines 14-26, the appellant submitted that the range of "80 to 110 consecutive days" for administration of the contraceptive active was based on a combination of the range of "60 to 110 consecutive days" and the preferred range of "80-90 days" as disclosed on page 8, lines 17-18 of the application as originally filed. In the appellant's view, it was established case law of the boards of appeal that parts of originally disclosed general and preferred ranges may be combined without introducing additional subject-matter.

With respect to the range of "5 to 8 days", the appellant pointed to page 8, line 20 of the application as originally filed. The appellant argued that since this was the preferred range for the administration-free interval, the combination of the "80 to 110 days" with "5 to 8 days" was directly and unambiguously derivable from page 8, lines 14-20 of the application as originally filed and did not require any selection from two lists.

X. The respondents' (opponents 1 and 2) arguments, insofar as they are relevant to the present decision, can be summarised as follows:

The respondents did not raise any objections to the admissibility of the requests filed with the letter of 15 June 2007.

However, the respondents' argued that the auxiliary requests 5 and 6, filed during oral proceedings, should not be admitted into the proceedings in view of the lateness of their introduction and in view of the numerous requests that had already been filed by the appellant in the course of the opposition and opposition appeal proceedings.

In the respondents' view, the features introduced into claim 1 of each of the requests filed with the letter of 15 June 2007 were not directly and unambiguously disclosed in combination in the patent application as originally filed and, therefore, the subject-matter of said requests contravened Article 123(2) EPC.

XI. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request or alternatively on the basis of one of the auxiliary requests 1-4 all filed with the letter of 15 June 2007.

The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of late-filed requests*

2.1 The admissibility of the requests filed with the letter of 15 June 2007 was not contested by the respondents. Since said requests were clearly filed as a direct response to the communication sent as an annex to the invitation to oral proceedings, the board sees no reason to differ.

2.2 The auxiliary requests 5 and 6 filed during oral proceedings were, however, not admitted into the proceedings for the following reasons:

The admissibility of late-filed requests is at the board's discretion and depends upon the overall circumstances of the case under consideration, a general principle being that the later requests are filed, the less likely they are to be held admissible.

The wording introduced into claim 1 of auxiliary request 5, namely, "followed by non-administration, said non-administration comprising administration of a placebo", raises new issues of clarity at a very late stage in the procedure.

In claim 1 of auxiliary request 6 reference to administration of a placebo has been deleted. However, this feature was present in all the claims filed with the letter of 15 June 2007 and relied on by the

appellant in its arguments with respect to novelty and inventive step. A shifting of the invention cannot be justified at such a late stage in the proceedings.

Moreover, as outlined above, different amendments have been introduced by the appellant into auxiliary requests 5 and 6, which relate to daily doses of 30 and 20 mcg of ethinyl estradiol (or equivalent), respectively. These amendments go in different directions from one another and cannot be viewed as a logically clear and consistent response to any objections raised for the first time during oral proceedings.

3. *Article 123(2) EPC*

3.1 In order to assess whether the requirements of Article 123(2) EPC have been met in the present case, it appears to be helpful to cite claim 1 as originally filed, which read as follows:

"1. A method of female contraception which comprises monophasicly administering a combination of estrogen and progestin for 60-110 consecutive days in which the daily amounts of estrogen and progestin are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively, following [sic] by non-administration for a period of 3-10 days."

3.2 *Main request and auxiliary requests 1 and 2*

3.2.1 Claim 1 of the main request differs from claim 1 as originally filed inter alia in that it requires

administration of **tablets** comprising a combination of estrogen and progestin for **84** consecutive **days** followed by administration of a **placebo** for a period of **7 days**.

It can be acknowledged that in the application as originally filed the term "placebo" is used in the sense generally accepted in the contraceptive art, namely, tablets that are devoid of active contraceptive agent. This can be inferred from the references in the application as originally filed to the conventional combined oral contraceptives available in 21-day pill packs together with 7 placebo pills (see page 4, lines 5-6 and page 13, lines 18-24). The placebo interval is distinguished from the "pill free" interval in which nothing is administered in the interval between administration of the contraceptive active (see page 4, lines 5-6).

Apart from in the above-mentioned passages on page 4, lines 5-6 and page 13, lines 18-24, the only other reference to placebos in the application as originally filed is on page 11, lines 7-14:

"The pharmaceutical formulations may be provided in kit form containing at least about 60, and preferably at least about 84 tablets, and up to 110 tablets, intended for ingestion on successive days. Preferably administration is daily for at least 60 days using **tablets** containing the both the estrogen and the progestin and then for at least 3 days with **placebo**" (emphasis added).

This is in fact the only disclosure of administration of tablets in combination with placebos as an

embodiment of the invention in the application as originally filed.

In the second sentence of the passage cited above, it is disclosed that the active tablets are administered daily for at least 60 days and the placebo for at least 3 days. This can be read in the context of the preceding sentence which discloses a kit wherein the number of tablets is preferably at least about 84.

However, nowhere in the application as originally filed can a clear and unambiguous basis be found for the regimen as claimed of administration of **active tablets for 84 days** followed by administration of a **placebo for 7 days**.

Hence, claim 1 of the main request contravenes the requirements of Article 123(2) EPC.

3.2.2 Contrary to the appellant's opinion, it cannot be accepted that the description as a whole provides a clear and unambiguous basis for the above-mentioned combination.

On page 8, lines 23-26 and page 14, lines 7-10, a schedule is disclosed of **84 days administration**; however, this is followed by **7 pill-free days** rather than placebo days.

The arguments of the appellant that the skilled person would understand that the 84/7 dosing regimen was not inextricably linked to a pill-free interval are relevant to the question of what might be rendered obvious by the content of the application as filed

taking into account the general knowledge of the skilled person. This must be clearly distinguished from the question of what has been directly and unambiguously disclosed by the application as filed.

Concerning Example 1, it is true that some of the monkeys were put on a schedule of ultra low doses of oral contraceptives for 84 consecutive days followed by a **7 non-treatment days** (page 12, lines 17-22). Firstly, however, the active contraceptive was not given in tablet form. Instead, the commercially available monophasic pill "Loestrin 1/20" was ground down to a powder to allow body-weight-adjusted doses to be given (page 13, lines 18-24). Secondly, although the "Loestrin 1/20" packs contained iron-containing placebos, these were not administered to the monkeys, since page 13, lines 5-6 clearly refers to a "pill free" interval. This was confirmed by the appellant at oral proceedings before the board. Therefore, this embodiment also does not provide a basis for the claimed combination.

3.2.3 Since claims 1 of auxiliary requests 1 and 2 also contain the regimen of administration of active tablets for 84 consecutive days followed by administration of a placebo for 7 days, the conclusions under points 3.2.1 and 3.2.2 apply equally to these requests.

Therefore, claims 1 of auxiliary requests 1 and 2 do not meet the requirements of Article 123(2) EPC.

3.3 *Auxiliary requests 3 and 4*

3.3.1 The method claimed in claim 1 of the third auxiliary request differs from that of claim 1 as originally filed in the following specific features:

- the way of administration of the actives is oral,
- the female subject is human,
- the contraceptive is in the form of a tablet comprising a combination of estrogen and progestin,
- the period of administration of the actives is 80 to 110 days, and
- the non-administration period is for 5-8 days during which a placebo is given.

The question that is to be decided is whether this combination of specific features can be directly and unambiguously derived from the application as originally filed.

The method of contraception disclosed in claim 1 as originally filed covers any female subject and does not specify the means of administration, or whether the estrogen and the progestin are to be administered together or separately. The actives are administered for 60-110 consecutive days followed by non-administration for a period of 3-10 days (cf. point 3.1).

In the dependent claims as originally filed, the only one of the above-mentioned features of claim 1 of the third auxiliary request disclosed is the lower limit of 80 days (see claim 10).

Turning to the description as originally filed, the "summary of the invention" largely reflects claim 1 as originally filed (see page 8, lines 1-12).

In the following section "description of the invention", the first paragraph discloses administration of a combined dosage form of estrogen and progestin for women in need of contraception for 60 to 110 consecutive days, preferably about 80-90 days, followed by an administration free interval of 3 to 10 days, preferably about 5-8 days. It is further stated that, on a schedule of 84 days administration followed by 7 pill free days, there are only four treatment and menstrual cycles per year (see page 8, lines 14-26).

Following a number of passages in the description detailing various preferred estrogens and progestins, dosage amounts and dosage forms (page 9, line 1 to page 11, line 6), a specific embodiment is disclosed in the paragraph on page 11, lines 7-14. The second sentence of said paragraph discloses the preferred administration of active tablets containing both estrogen and progestin for at least 60 days followed by the placebo for at least 3 days.

In order to arrive at the combination now claimed, the appellant has thus selected particular features from different parts of the application, namely, page 8, lines 14-26 and page 11, lines 7-14, and created a **novel specific combination**, which was relied upon by the appellant in its arguments in favour of novelty and inventive step (cf. patentee's letter of 15 June 2007, pages 9-14). An improvement of the appellant's position

by means of an unallowable selection is clearly contrary to the idea underlying Article 123(2) EPC.

3.3.2 Contrary to the appellant's arguments, a link between the use of tablets comprising a combination of estrogen and progestin and placebos, on the one hand, and the specific intervals of 80-110 and 5-8 days, respectively, on the other, is not directly and unambiguous derivable from the disclosure in the application as originally filed.

As explained above, the preferred intervals in the paragraph on page 8, lines 14-26 are disclosed for administration and administration-free intervals in a very general context, in particular, without specifying the precise mode of administration of the estrogen and progestin, respectively, or the precise nature of the administration-free interval.

It would therefore not have been directly and unambiguously apparent to a person skilled in the art reading the application as originally filed that the preferred intervals appearing on page 8 within a much more general context were also to be preferred for the particular embodiment disclosed on page 11, lines 7-14, i.e. for the mode of administration in the form of tablets containing both estrogen and progestin, followed by a period of administration of a placebo.

3.3.3 Since claim 1 of the fourth auxiliary request also comprises the feature of administration of active tablets for 80 to 110 consecutive days followed by administration of a placebo for 5 to 8 days, the

conclusions under points 3.3.1 and 3.3.2 apply equally to this request.

3.3.4 Accordingly, claims 1 of auxiliary requests 3 and 4 contravene Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend U. Oswald