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D E C I S I O N
of 22 March 1999

Case Number: T 0485/95 - 3.3.2

Application Number: 87306174.1

Publication Number: 0253607

IPC: A61K 31/565

Language of the proceedings: EN

Title of invention:
Combination dosage form for premenopausal women

Patentee:
American Home Products Corporation

Opponent:
Akzo Pharma B.V.

Headword:
Combination dosage forms/AMERICAN HOME PRODUCTS

Relevant legal provisions:
EPC Art. 54, 56, 84, 123(2), (3)

Keyword:
"Main, first and second auxiliary request - inventive step (no): reasonable expectation of success"
"Third auxiliary request - novelty and inventive step (yes)"
"Solution of the technical problem not obvious; inventive alternative"

Decisions cited:
T 0219/83

Catchword:
-

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Case Number: T 0485/95 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 22 March 1999

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 19 April 1995 concerning maintenance of European patent No. 0 253 607 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: G. F. E. Rampold
S. C. Perryman

Summary of Facts and Submissions

I. The appellant (opponent) originally filed notice of opposition to the grant of European patent No. 0 253 607 and requested its revocation as a whole on the ground that the subject-matter of the patent opposed was not patentable (Article 100(a) EPC) because it did not involve an inventive step (Articles 52(1); 56 EPC).

The opposition was based, *inter alia*, on the following citations:

(1) DE-A-3 347 125

(3) US-A-3 639 600

(7) EP-A-0 036 229

II. During the oral proceedings before the opposition division the respondent (proprietor of the patent) filed a first amended set of claims 1 to 17 for all designated contracting states except AT, ES, GR, a second amended set of claims 1 to 17 for the contracting states AT, ES, GR, in which in each case only independent claim 8 had been amended compared to the granted claims, and a consequentially amended description.

The independent claims 1 and 8 of the first set of 17 claims as granted for all designated contracting states except AT, ES, GR, read as follows:

"1. The use of a composition comprising an estrogen selected from

0.5 - 2.0 mg of 17 β-estradiol
0.008 - 0.030 mg of ethinyl estradiol, and
0.015 - 0.060 mg of mestranol;
and a progestogen selected from
0.025 - 0.100 mg of levonorgestrel,
0.010 - 0.070 mg of gestodene,
0.025 - 0.100 mg of desogestrel,
0.025 - 0.100 mg of 3-ketodesogestrel, and
0.085 - 0.35 mg norethindrone,

for the manufacture of a dosage form for providing hormonal replacement therapy and contraception for a pre-menopausal woman by administration of the dosage form for 23 to 26 days beginning at day one of the menstrual cycle, followed by 2 to 5 pill-free or blank pill days, for a total of 28 days in the administration cycle."

"8. A pack for providing a hormonal replacement therapy and contraception for a pre-menopausal woman which pack comprises

(a) 23 to 26 dosage forms each comprising an estrogen selected from:

0.5 - 2.0 mg of 17 β-estradiol
0.008 - 0.030 mg of ethinyl estradiol, and
0.015 - 0.060 mg of mestranol;
and a progestogen selected from

0.025 - 0.100 mg of levonorgestrel
0.010 - 0.070 mg of gestodene
0.025 - 0.100 mg of desogestrel
0.025 - 0.100 mg of 3-ketodesogestrel, and
0.085 - 0.35 mg norethindrone

and

(b) 2 to 5 blank pills or other indications to indicate that the daily administration of the 23 to 26 dosage forms should be followed by 2 to 5 pill free or blank pill days."

The differences in amended claim 8 compared to its wording as granted are set out below with additions being indicated in bold italic letters and omissions crossed through and other parts of the claim remaining the same:

"8. A pack .... which pack comprises

(a) 23 to 26 dosage forms each ~~comprising~~ ***of which is the same and comprises*** an

.....

.....

and

(b) 2 to 5 blank pills or other indications to indicate that the daily administration of the 23 to 26 dosage forms should be followed by 2 to 5 free or blank pill days ***for a total of 28 days in the administration cycle.***

Claims 2 to 7 were dependent on claim 1 and related to specific embodiments of the use according to claim 1. Claims 9 to 17 were dependent on claim 8 and related to specific embodiments of the pack according to claim 8.

III. In an interlocutory decision given 9 February 1995 with the written grounds for the decision posted 19 April 1995 the opposition division reached the conclusion that the patent as amended met the requirements of the EPC (Article 102(3)EPC) and decided to maintain the patent as amended. In particular, it found the amended

claim 8 set out in point II above acceptable under the terms of Articles 84 and 123(2) and (3) EPC and noted that the novelty of the claimed subject-matter in the patent in suit had not been contested by the opponents.

As far as inventive step was concerned the opposition division considered citation (1) to be the closest state of the art and also referred to citations (3) and (7). It found that the cited prior art in its entirety was concerned with multi-phase regimens whereas the claims of the patent after amendment only extended to mono-phasic regimens. Hence, the opposition division took the view that none of the cited documents, either taken individually or in combination, suggested to the skilled person, faced with the problem of providing hormonal replacement therapy and contraceptive protection of the pre-menopausal woman, the solution of this problem by modifying the regimen disclosed in citation (1) in the way proposed in the contested patent, and concluded that the claimed subject-matter in the patent in suit involved an inventive step.

IV. The appellant filed an appeal against the decision of the opposition division and requested revocation of the patent as a whole on the grounds that the subject-matter of the patent as amended during opposition proceedings was not patentable under Article 100(a) EPC, because of lack of novelty of claims 8 to 17 (Articles 52(1); 54 EPC) and lack of inventive step of all claims 1 to 17, and that the subject-matter of claims 8 to 17 as amended during opposition proceedings extended beyond the content of the application as filed (Article 123(2) EPC).

Together with the statement of grounds for appeal the appellant additionally introduced, *inter alia*, the following citations:

(11) US-A-3 939 264

(12) US-A-3 957 982

(13) US-A-3 969 502

(14) EP-A-0 136 011

(15) EP-A-0 235 090

V. In advance of the oral proceedings scheduled for 19 March 1999 the respondent submitted by fax dated 19 February 1999 a declaration by a Professor J. Guillebaud and four abstracts (94, 95, P. 2.19, P. 2.20) which appeared in the European Journal of Contraception and Reproductive Health Care 1998, Sponsored Symposia, and which referred to a symposium conducted in 1998. In addition, it filed a main request and auxiliary requests each of which included a first set of claims for the designated contracting states except AT, ES, GR, and a second set of claims for the contracting states AT, ES, GR.

VI. During the oral proceedings the respondent filed second and third auxiliary requests:

(i) According to the **first auxiliary request** filed 19 February 1999 only independent claim 8 for the states other than AT, ES and GR differed from the claims for these states as granted, the difference being the addition at its end of the words:

"..***for a total of 28 days in the administration cycle, provided each of the dosage forms comprises the same amount of estrogen and the same amount of progestogen.***

(ii) According to the **second auxiliary request** filed during oral proceedings claim 1 for the states other than AT, Es and GR differs from claim 1 as granted for these other states, the differences being set out below with additions being indicated in bold italic letters and omissions crossed through and other parts of the claim 1 remaining the same:

"1. The use of a composition comprising an estrogen selected from:

0.75 ~~0.500~~ **- *1.50*** ~~2.000~~ mg of 17 β-estradiol
0.012 ~~0.008~~ - ***0.025*** ~~0.030~~ mg of ethinyl estradiol, and
0.025 ~~0.015~~ - ***0.050*** ~~0.060~~ mg of mestranol;
....
...."

Other claims in the second auxiliary request were also amended.

(iii) According to the **3rd auxiliary request** filed during the oral proceedings independent claims 1 and 8 for the states other than AT, ES and GR differed from the claims for these states as granted. The differences in amended claims 1 and 8 compared to their wording as granted are set out below with additions being indicated in bold italic letters and omissions crossed through and other parts of the claims remaining the same:

"1. The use of a composition comprising an estrogen selected from:
0.75 ~~0.500~~ **- *1.50*** ~~2.000~~ mg of 17 β-estradiol
0.012 ~~0.008~~ - ***0.025*** ~~0.030~~ mg of ethinyl

estradiol, and
0.025 ~~0.015~~ - *0.050* ~~0.060~~ mg of mestranol;
and a progestogen selected from:
0.035 ~~0.025~~ - *0.085* ~~0.100~~ mg of levonorgestrel,
0.015 ~~0.010~~ - *0.060* ~~0.070~~ mg of gestodene,
0.035 ~~0.025~~ - *0.085* ~~0.100~~ mg of desogestrel,
0.035 ~~0.025~~ - *0.085* ~~0.100~~ mg of
3-ketodesogestrel, and
0.10 ~~0.085~~ - *0.30* ~~0.35~~ mg of norethindrone

for the manufacture of a dosage form for providing hormonal replacement therapy and contraception for a pre-menopausal woman by administration of the dosage form for 23 to 26 days beginning at day one of the menstrual cycle, followed by 2 to 5 pill-free or blank pill days, for a total of 28 days in the administration cycle."

Claim 1 is followed by dependent claims 2 to 7 relating to specific embodiments of the use according to claim 1.

"8. A pack for providing a hormonal replacement therapy and contraception for a pre-menopausal woman which pack comprises

(a) 23 to 26 dosage forms each comprising an estrogen selected from:
0.75 ~~0.500~~ - *1.50* ~~2.000~~ mg of 17 β-estradiol
0.012 ~~0.008~~ - *0.025* ~~0.030~~ mg of ethinyl estradiol, and
0.025 ~~0.015~~ - *0.050* ~~0.060~~ mg of mestranol;
and a progestogen selected from
0.035 ~~0.025~~ - *0.085* ~~0.100~~ mg of levonorgestrel,
0.015 ~~0.010~~ - *0.060* ~~0.070~~ mg of gestodene,
0.035 ~~0.025~~ - *0.085* ~~0.100~~ mg of desogestrel,

0.035 ~~0.025~~ - ***0.085*** ~~0.100~~ mg of 3-ketodesogestrel, and
0.10 ~~0.085~~ - ***0.30*** ~~0.35~~ mg norethindrone
and

(b) 2 to 5 blank pills or other indications to indicate that the daily administration of the 23 to 26 dosage forms should be followed by 2 to 5 pill-free or blank pill days, ***for a total of 28 days in the administration cycle.***

This request also contains claims 2 to 7 dependent on claim 1 and relating to specific embodiments of the use according to claim 1, and claims 8 to 17 dependent on claim 8 and relating to specific embodiments of the pack according to claim 8.

VII. The appellant's submissions both in the written procedure and at the oral proceedings can be summarised as follows:

- Contrary to the finding of the opposition division, the limitation of claim 8 as amended during the first instance opposition proceedings to mono-phasic regimens, requiring that each of the 23 to 26 dosage forms in the 28 days' administration cycle was the same, contravened the provisions of Article 123(2) EPC.

- The first auxiliary request contained *de facto* the same limitation as the main request. Neither request was therefore acceptable under the terms of Article 123(2) EPC.

- Even if the amendment to claim 8 were to be considered acceptable by the board, the subject-matter of claim 8 lacked novelty over the state of the art according to citation (14), on the one hand, and citation (15) on the other.

- Claim 1 was directed to a so-called second medical indication and the essential technical feature was the use of the claimed dosage regimen for the combined contraceptive and HRT treatment in pre-menopausal woman. The regimen proposed in claim 1 of the patent in suit for this combined therapy was disclosed in (14) for HRT and in (11) for contraceptive protection. The skilled person faced with the problem of treating hormonal deficiencies and, at the same time, providing contraceptive protection, would combine the teachings of (11) and (14) and thus arrive at the claimed invention. The combination of the teachings of citations (13) and (14) or (7) and (14) or (1) and (14) would literally lead to the same result, ie the present invention. No inventive step was therefore recognisable for the subject-matter of claims 1 to 7.

VIII. The respondent's submissions both in the written procedure and at the oral proceedings can be summarised as follows:

- The opposition division gave in its decision a reasoned statement why the restriction to mono-phasic regimens was allowable. The present amendment was merely a clarifying amendment to make even more clear what the respondent regarded as already clear in the original specification.

- There was a clear basis in the specification as filed for the dosage forms to be identical even if there was a dispute as to whether there was also a basis for the dosage forms to be different. The specification contained specific disclosures showing that the dosage forms were identical. The passage quoted in the decision of the opposition division stated that, *inter alia*, a particularly preferred dosage form contained a specific amount of a particular estrogen or a particular progestogen. This meant necessarily that all the dosage forms of this particular aspect of the invention (ie "pack" or "use") contained the same amounts of the particular active ingredients and there was no other way of construing this statement. Claim 17 was another part of the originally filed specification which clearly stated that the pack comprised 23 dosage forms, each comprising a particular amount of a particular progestogen.

- Claim 1 as it stood was also a clear disclosure that a certain composition was used for the manufacture of a dosage form for providing HRT (hormone replacement therapy) and contraception by administration of **the** dosage form for 23 to 26 days. The wording "the dosage form" referred to the earlier occurrence of "a dosage form" which was in the singular. Thus, each of the dosage forms which were administered for 23 to 26 days had necessarily the same constitution as the dosage form that was referred to as "a dosage form". In other words, each of the dosage forms administered for 23 to 26 days had to be the same.

- If the respondent had wished to cover the situation where the dosage units could be the same or different it would have been easy to draft such a claim, for example, by amending the claim to make it clear that "each dosage form being the same or different".

- The claims of the main request and 1st auxiliary request were novel in view of the clarification that the claims only extended to mono-phasic regimens. The 2nd and 3rd auxiliary requests related to particular regimens which were novel over any mono-phasic and multi-phasic regimens known in the art, with or without the clarifying amendment.

- The technical problem was to provide an effective and safe contraceptive regimen for woman experiencing pre-menopausal symptoms or anovulatory cycles which regimen also provided a protective HRT effect. It was important to oppose estrogen in anovulatory cycles for safety reasons to minimise the risk of cardiovascular problems, and breast and endometrial cancer. However, it was not suitable to give a conventional HRT product, because these products did not contain sufficient hormone to provide effective contraceptive control, and it was not suitable to give a normal dose contraceptive, because in older women such contraceptive was associated with a higher risk of disorders such as cardiovascular disease.

- The problem was solved by providing an ultra low dose mono-phasic hormonal regimen in which both the estrogen and the progestogen components were lower than previously contemplated, and to shorten the pill free period, i.e extend the number of days on which active hormone was provided.

- The successful solution of the problem to be solved was unexpected: firstly because there was a clear prejudice against reducing both the estrogen and progestogen content of the contraceptive because of potential loss of contraceptive effect; secondly, at the priority date of the patent in suit there was no information in the art as to the effects of shortening the pill free period.

IX: The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested as main request that the appeal be dismissed and as auxiliary requests that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims entitled "1st Auxiliary Request" submitted on 19 February 1999 or the set of claims entitled "2nd Auxiliary Request" or "3rd Auxiliary Request" both submitted at the oral proceedings on 19 March 1999.

Reasons for the Decision

1. The appeal is admissible.

2. Claim 1 of both the main and the first auxiliary requests is still worded as granted, and was opposed only on the ground of obviousness. If the appellant's contention that this claim 1 lacks inventive step is correct, then the main and first auxiliary requests must be refused as a whole. It would then serve no useful purpose to deal with the issues under Articles 123 and 84 EPC in relation to claim 8 of the main request arising out of an amendment, found allowable by the opposition division but objected to by the appellant, which amendment is not present in the

claim 8 put forward in the second and third auxiliary requests, even though these issues took up much time in the appeal proceedings. Accordingly the board will consider the issue of obviousness of claim 1 first.

Main and first auxiliary request: claim 1 - obviousness

The closest state of the art

3. The invention relates to a dosage form for hormonal replacement therapy and contraception for pre-menopausal women using an estrogen combined with a progestogen. Dosage forms using an estrogen/progestogen combination ("e/p-combination") were known at the priority date both for the purpose of hormonal replacement therapy and for contraception, but a single medication for both purposes for pre-menopausal women is not shown in the cited art.

4. (14) refers to a method of e/p combination oral hormonal replacement treatment for the therapy of disorders in peri-menopausal woman. The term "peri-menopausal" is defined in (14) as "over approximately forty years of age" (see page 1, line 11) and refers to women of approximately forty years of age or older, who have not definitely arrived at menopause but who are experiencing symptoms associated with menopause (see page 4, lines 5 to 7). The period termed peri-menopausal in (14) corresponds exactly and in every aspect to the period termed "pre-menopausal" in the patent in suit (see especially column 2, lines 14 to 30) and the HRT treatment of (14) is accordingly directed to the same group of patients as is envisaged in the patent in suit.

5. The passage in (14) relating to directions, which might be applied to such a HRT multi-preparation pack, entitled "About these Tablets" (see page 16, especially

lines 10 to 12) states that the tablet disclosed in (14) "is used to control menopausal symptoms but is **not** a birth control pill and cannot relied upon to prevent pregnancy. Oral contraceptives should not be taken at the same time as these tablets and, if necessary, you should ask your doctor about alternative means of mechanical protection." Clearly this is inconvenient for the user, so document (14) can fairly be said to set the skilled person the problem of providing an alternative to what is suggested in (14) which alternative will serve as both a HRT and as a contraceptive. It is not part of the problem that such alternative be better than or even as good a HRT as that suggested in document (14): there is no evidence before the board that this is so. Rather the alternative must merely be better than no HRT at all. As a contraceptive it must however be reliable.

6. The invention of claim 1 suggests solving this problem by the provision of e/p combination therein defined for 23 to 26 days of a 28 day cycle.

7. The patent in suit claims that regimens falling within claim 1 solve this problem. During oral proceedings, the appellant suggested that it was doubtful whether every regimen covered by the claim would provide contraceptive reliability, but did not substantiate this by any evidence. If use were impossible this would have been something that could have been raised as an objection under Article 100(b) EPC, but the appellant did not do so in his opposition so the matter could not be considered as a new issue on appeal without the patentee's consent. A mere doubt cannot prevent the statement in the patent that what is claimed is effective being taken into account when formulating the problem. As stated in decision T 219/83 (BASF/Zeolites OJ EPO 1986, 211) if the parties to opposition

proceedings make contrary assertions which they cannot substantiate and the European Patent Office is unable to establish the facts of its own motion, the patent proprietor is given the benefit of the doubt. The board can thus accept that the subject matter of claim 1 plausibly solves the problem.

8. The method disclosed in (14) involves the continuous and uninterrupted administration of very small doses of a progestogen (0.025 to 0.075 mg preferably 0.05 mg levonorgestrel, see page 9, Table 1B) along with administration of small doses of an estrogen (for example 0.005 - 0.020 ethinyl estradiol see page 8 table 1A). These are preferably given continuously, but where required, for example, with peri-menopausal woman, the administration of the estrogen can be cyclical usually between 20 and about 120 days with an off period of between about 3 and 7 days (top of page 4).

9. The first step the skilled person would take would be to note the existing suggested contraceptive(s) that come closest to the HRT of (14). Here the skilled person will find in document (13) a suggested regimen

First phase (10-12 days):
0.025 - 0.035 mg of 17 α-ethinyl estradiol;
0.050 - 0.125 mg of d-norgestrol (= levonorgestrel;

Second phase (11-9 days):
0.030 - 0.050 mg of 17 α-ethinyl estradiol;
0.100 - 0.350 mg of levonorgestrel;
(see column 2, lines 38 to 66; ; example 1);
the administration period of the estrogen/progestogen combination oral contraceptive is 19-23 days maximum followed by 5-7 placebos for a total of 28 days in the administration cycle (see column 2, line 1 to 12; column 4, lines 21 to 34).

10. To choose a contraceptive falling within the limits suggested by document (13) while matching the HRT of (14) as closely as possible the skilled person would as a first step select the lowest values for ethinyl estradiol and levonorgestrel and the administration period of 23 days (closest to continuous administration) to arrive at a regimen:

First phase (10-12 days):
0.025 mg of ethinyl estradiol;
0.050 mg of levonorgestrel;

Second phase (11-9 days):
0.030 mg of ethinyl estradiol;
0.100 mg of levonorgestrel;

The total regimen would be for 23 days of a 28 day cycle.

The skilled person would have a every expectation of success that it would work as a contraceptive, as it falls within what (13) teaches is an effective contraceptive, and the closeness to (14) would give him a reasonable expectation of success that this regimen would serve as a HRT.

11. As a second stage in developing a new regimen, the skilled person might modify the regimen of point 10 above by modifying one parameter at a time in the direction of (14), for example changing or increasing the number of days from 23 to 24 in the cycle, or reducing the ethinyl estradiol to 0.025 mg in the second phase of the cycle, the same as in the first phase in the direction of the lower central value for ethinyl estradiol suggested in (14).

12. The respondent has sought to argue that it is an implicit feature of claim 1 that it relates to a composition in which each daily dosage form is the "same", and that the claim does not cover multi-phasic dosage forms. Such a limitation is not one the board is prepared to read into the claim, nor does it see any clear and unambiguous basis for saying that this feature is disclosed at all in the patent. No such statement is to be found in the application as filed. All that the respondent has shown is that it might be obvious to a skilled person from reading the description that the teaching allows each daily dosage to be the same, but this is no reason to imply such a limitation into the description and claims.

13. Comparing now the regimen set out in point 10 which regimen the board considers the skilled person would derive in an obvious manner from the prior art, each of the regimens for the first and second phase falls within the numerical ranges stated in claim 1 for ethinyl estradiol and levonorgestrel respectively stated, as does the dosage cycle of 28 and the number of pill free days, five, in this cycle. Thus the skilled person will arrive in an obvious manner at something falling within the claim 1 of both the main request and the first auxiliary request. Thus neither of these requests are allowable.

Second auxiliary request: claim 1

Scope after amendment, basis and clarity

14. In comparison with claim 1 as granted, claim 1 of this request is restricted to narrower and lower ranges of the amounts of the diverse estrogens used as can be see in point VI.(ii) above. The more restricted limits on

the amounts of estrogen used means that this amended claim 1 complies with the requirement of Article 123(3) EPC that claims may not be amended during opposition proceedings (and on an appeal in such proceedings) in such a way as to extend the protection conferred.

15. The amendment finds a basis in the application as filed in the passage on page 5, lines 16 to 20 of the application as filed disclosed with reference to all "aspects of the invention" and independently of the dosage ranges of the progestogen components. Consequently amended claim 1 complies with the requirements of Article 123(2) EPC.

16. No objection under Article 84 EPC to the clarity of this amended claim has been raised by the appellant and the board sees none.

Novelty

17. No objection under Article 54 EPC to the novelty of this amended claim has been raised by the appellant and the board sees none.

Inventive Step

18. For the purposes of assessing inventive step, the closest prior art and the problem to be solved remain as set out in points 3 to 5 above. For the reasons given in point 7 above the board can also accept that the subject matter of claim 1 of this request plausibly solves the problem.

19. Following the same analysis for the purpose of assessing inventive step, and considering what the skilled person would do to solve the problem, as set out in points 8 to 11, in particular the second stage of development discussed in point 11, the skilled person, who reduces the ethinyl estradiol in phase two to achieve something closer to (14) arrives at:

First phase (10-12 days):
0.025 mg of ethinyl estradiol;
0.050 mg of levonorgestrel;

Second phase (11-9 days):
0.025 mg of ethinyl estradiol;
0.100 mg of levonorgestrel;

The total regimen would be for 23 days of a 28 day cycle.

20. Comparing now the regimen set out in point 19 with claim 1 of this request, each of the regimens for the first and second phase falls within the numerical ranges stated in claim 1 for ethinyl estradiol and levonorgestrel respectively stated, as does the dosage cycle of 28 days and the number of pill free days, five, in this cycle. Thus the skilled person will arrive in an obvious manner at something falling within the claim 1 of this second auxiliary request. Thus this request is not allowable.

Third auxiliary request

Scope after amendment, basis and clarity

21. In comparison with claims 1 and 8 as granted, the claims 1 and 8 of this request are restricted to narrower and lower ranges of the amounts of the diverse estrogens and progestogens used as can be seen in point

VI.(iii) above, and at the end of claim 8 is added the restriction "for a total of 28 days in the administration cycle". These more restricted limits on the amounts of estrogen and progestogen used and the length of the cycle mean that these amended claims comply with the requirement of Article 123(3) EPC that claims may not be amended during opposition proceedings (and on an appeal in such proceedings) in such a way as to extend the protection conferred.

22. The amendments find a basis in the application as filed in the passage on page 5, lines 16 to 20 of the application as filed disclosed with reference to "all aspects of the invention" and are also based on a combination of claims 1 and 5 as filed, or respectively claims 8 and 11 as filed. The additional words at the end of claim 8 find a basis on page 1 of the description as filed. Consequently the amended claims 1 and 8 comply with the requirements of Article 123(2) EPC.

23. Claims 2 to 7 are dependent on claim 1 and are based on claims 2 to 4, 6 and 7 as filed and granted. Claims 9 to 17 are dependent on claim 8 and are based on claims 9, 10 and 12 to 17 of the application as filed and granted. Consequently, all claims are adequately supported by the disclosure of the application as filed and they do not extend beyond the scope of the claims as granted. Thus the dependent claims of this request meet the requirements of Article 123(2) and (3) EPC.

24. No objection under Article 84 EPC to the clarity of any amended claims has been raised by the appellant and the board sees none.

Novelty

25. No objection under Article 54 EPC to the novelty of these amended claims has been raised by the appellant and the Board sees none.

Inventive Step

26. For the purposes of assessing inventive step, the closest prior art and the problem to be solved and what the skilled person would do remain as set out in points 3 to 5 above.

27. The same problem is now solved by the more restricted compositions set out in claim 1 of this request (see point VI.(iii)). These fall wholly within the compositions for which it has been stated in point 7 above that the problem has been plausibly solved, and accordingly for the same reasons the problem can be regarded as solved by what is covered by this claim 1.

28. Following the same analysis for the purpose of assessing inventive step, and considering what the skilled person would do to solve the problem, as set out in points 8 to 11, the board does not consider that the skilled person would arrive in an obvious manner at something falling within claim 1 of this request. Once the skilled person has followed the line set out in point 10 above, the board can accept that he would reduce the amount of one component, in particular the estrogen component, and still retain a reasonable expectation that the contraceptive effect would hold, but not that he would reduce the amount of both the estrogen and, in particular, the progestogen component, with any reasonable expectation of success. In the board's opinion, the skilled person would not reasonably have considered the possibility of reducing the upper limit of levonorgestrel to a dose level of

0.085 mg/day maximum while reliably maintaining the contraceptive effect. This finding appears particularly surprising on the basis that a combined preparation containing both ethynyl estradiol and levonorgestrel at dose levels roughly corresponding to those in claim 1 of this request was not considered in (14) to have the capability of preventing pregnancy. Accordingly inventive step can be acknowledged for claim 1 of this request.

29. Claim 8 is directed to a pack which might cover such a pack even for some other therapeutic purpose. The same arguments must be applied for claim 8 as for claim 1.

30. The other claims are dependent on claim 1 or 8 respectively, being directed to specific embodiments of the inventions claimed in these claims. Accordingly as inventive step has been acknowledged for the independent claims, it can be acknowledged also for the dependent claims.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the set of claims entitled 3rd Auxiliary Request submitted at the oral proceedings on 19 March 1999 and a description to be adapted.

The Registrar: The Chairman:

M. Dainese U. Oswald