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Datasheet for the decision of 23 November 2020

Case Number: T 2552/16 - 3.3.01

Application Number: 09706347.3

Publication Number: 2252301

IPC: A61K31/57, A61P5/36, A61P15/00

Language of the proceedings: EN

Title of invention:
USE OF ULIPRISTAL FOR TREATING UTERINE FIBROIDS

Patent Proprietor:
The U.S.A. as represented by the Secretary,
Department of Health and Human Services
Laboratoire HRA Pharma

Opponents:
Helm AG
Generics [UK] Ltd (trading as Mylan)

Headword:
Ulipristal for treatment of fibroid-associated bleeding/USA & HRA PHARMA

Relevant legal provisions:

EPC Art. 56, 123(2)
EPC R. 115(2)
RPBA 2020 Art. 15(3)

Keyword:

Inventive step - (no)
Amendments - allowable (no)
Oral proceedings - held in absence of party

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2552/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 23 November 2020

Appellant: (Patent Proprietor 1)	The U.S.A. as represented by the Secretary, Department of Health and Human Services Office of Technology Transfer National Institutes of Health 6011 Executive Boulevard, Suite 325 MSC 7660 Bethesda, MD 20892-7660 (US)
Appellant: (Patent Proprietor 2)	Laboratoire HRA Pharma 15, rue Béranger 75003 Paris (FR)
Representative:	Chajmowicz, Marion Becker & Associés 25, rue Louis Le Grand 75002 Paris (FR)
Respondent: (Opponent 2)	Generics [UK] Ltd (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1 AG (GB)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 11 October 2016 revoking European patent No. 2252301 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	P. de Heij

Summary of Facts and Submissions

I. European patent 2252301 is based on application 09706347.3, which was filed as an international application and published as WO 2009/095418. The patent is entitled "Use of ulipristal for treating uterine fibroids" and was granted with 12 claims.

Claim 1 as granted reads as follows:

"1. Ulipristal acetate (17α-acetoxy-11β-[4-N, N-dimethylamino-phenyl)-19-norpregna- 4, 9-diene-3, 20-dione) or any metabolite selected from the group consisting of CDB-3877, CDB-3963, CDB-3236, and CDB-4183, for use in reducing or stopping bleedings in a patient suffering from uterine fibroids."

II. Two oppositions were filed against the patent as granted, both opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC). Opponent 1 later withdrew its opposition, so opponent 2 became the sole opponent.

III. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D1 Lefebvre et al. 2003, SOCG Clinical Practice Guidelines

D3 Levens et al. 2007, Reprod. Sciences 14(1, Suppl.) Meeting abstract 82

D8 Chabbert-Buffet et al. 2007, J. Clin. Endocrinol. Metab. 92(9): 3582-3589
D15 Buttram and Reiter 1981, Fertility & Sterility 36(4): 433-445
D18 Donnez et al. 2012, N. Engl. J. Med. 366(5): 421-432
D19 Sulaiman et al. 2004, Eur. J. Obstetr. & Gynec. and Reprod. Biol. 115: 85-89
D23 Declaration of Prof. Jacques Donnez, 2015

IV. By its decision pronounced at oral proceedings, the opposition division revoked the patent under Article 101(2) and 101(3)(b) EPC.

The opposition division decided that the sets of claims according to the main request (claims as granted) and auxiliary requests I to V all lacked inventive step.

V. The patent proprietors (appellants) lodged an appeal against that decision. With the statement of the grounds of appeal, the appellants requested that the patent be maintained as granted (main request) or, alternatively, according to auxiliary requests I to VII, all filed with the grounds of appeal.

The **main request** consists of the claims as granted.

Claim 1 of **auxiliary request I** differs from claim 1 of the main request in that the following feature was added:

"..., wherein bleedings are a symptom of uterine fibroids in said patient."

In **auxiliary request II**, claim 1 of the main request was amended by adding the feature "at a daily dosage of 5 mg to 15 mg."

Auxiliary request III combines the amendments of auxiliary requests I and II: "at a daily dosage of 5 mg to 15 mg, wherein bleedings are a symptom of uterine fibroids in said patient."

In **auxiliary request IV**, claim 1 of the main request was amended by adding the feature "at a daily dosage of 5 mg."

Auxiliary request V combines the amendments of auxiliary requests I and IV: "at a daily dosage of 5 mg, wherein bleedings are a symptom of uterine fibroids in said patient."

Claim 1 of **auxiliary request VI** differs from claim 1 of the main request in that it has been amended as shown:

"1. Ulipristal acetate (17α-acetoxy-11β-[4-N, N-dimethylamino-phenyl)-19-norpregna- 4, 9-diene-3, 20-dione) ~~or any metabolite selected from the group consisting of CDB-3877, CDB-3963, CDB-3236, and CDB-4183,~~ for use in reducing or stopping bleedings in a patient suffering from uterine fibroids at a daily dosage of 5 mg by oral route, wherein bleedings are a symptom of uterine fibroids in said patient."

Claim 1 of **auxiliary request VII** differs from claim 1 of the main request in that it has been amended as shown:

"1. Ulipristal acetate (17α-acetoxy-11β-[4-N, N-dimethylamino-phenyl)-19-norpregna- 4, 9-diene-3, 20-

dione) ~~or any metabolite selected from the group consisting of CDB-3877, CDB-3963, CDB-3236, and CDB-4183,~~ for use in reducing or stopping bleedings in a patient suffering from uterine fibroids, wherein bleedings are a symptom of uterine fibroids in said patient, ulipristal acetate is administered daily by oral route and bleedings are stopped or reduced after the administration of ulipristal acetate for one menstrual cycle."

VI. The opponent (respondent) replied by letter dated 15 September 2017.

VII. A summons to oral proceedings before the board was issued, followed by a communication pursuant to Article 15(1) RPBA providing a preliminary opinion on the admission of late-filed requests and documents.

VIII. By letter dated 16 April 2020, the respondent withdrew its request for oral proceedings. By letter dated 23 September 2020, the appellants gave notice that they would not be represented at oral proceedings.

IX. Oral proceedings before the board took place on 23 November 2020 as scheduled, in the absence of the parties. At the end of the oral proceedings, the chairman announced the board's decision.

X. The appellants' submissions, submitted in writing and in so far as relevant for the present decision, may be summarised as follows:

Main request and auxiliary requests I to III: inventive step

The closest prior art was document D1, not D3, because D3 was not concerned with the same technical problem as the claimed subject-matter, i.e. treating bleedings in patients with uterine fibrosis, but rather related to treating uterine fibrosis with the aim of reducing fibroid size. D3 did not disclose or suggest the patient subgroup of the invention, namely patients suffering from bleedings as a symptom of uterine fibroids. It was apparent from D1 and D15 that bleedings were not a ubiquitous symptom of uterine fibrosis, being present in only about 30% of symptomatic patients. D3 was totally silent on alleviating bleedings associated with uterine fibrosis; the reported amenorrhea meant that the ulipristal treatment could suppress normal, physiological menstruation, but there was no teaching that the treatment would be effective in stopping or reducing pathological bleeding associated with uterine fibrosis, which was a different clinical situation. D3 was not an appropriate starting point for the problem-solution approach.

For the sake of argument, however, starting from document D3 the technical problem had to be formulated as providing a new therapeutic use of ulipristal acetate.

Contrary to the opposition division's conclusions, the experimental evidence disclosed in the patent was not equivalent to that in D3. Document D3 did not teach that patients had to suffer from bleedings in order to be included, nor that alleviating bleedings was a possible endpoint of the study. It merely taught the effect of the treatment on reducing fibroid size. At the priority date, however, the skilled person would have known that there was no correlation between

fibroid size and excessive bleeding (D15, Table 1 and page 441, column 2; D23, page 3, last paragraph), or even a negative correlation (D19, Figure 2). When reading D3, the skilled person would not know whether women with bleedings as a symptom of uterine fibroids were treated with ulipristal. At best D3 would teach the skilled person that ulipristal acetate is able to block normal menstruation. The skilled person would not deduce from D3 that ulipristal acetate might be of interest for stopping bleedings in patients suffering from uterine fibroids. The skilled person would thus not derive from D3 any expectation of success of using ulipristal acetate to treat bleedings as a symptom of uterine fibroids.

Auxiliary requests IV to VI: inventive step

Neither D3 nor D8 provided any motivation to use ulipristal acetate at a dosage of 5 mg to treat bleedings in patients with uterine fibrosis. In fact, D8 taught administering ulipristal acetate as a contraceptive at 2.5 mg, 5 mg and 10 mg for healthy women with regular menstrual cycles. Accordingly, D8 was totally irrelevant for the claimed invention. Even in the context of contraception, it was clear from D8 that a 5 mg dosage did not have the same effect as a 10 mg dosage since it was less effective at producing amenorrhea (Table 3 of D8), and that it caused more adverse effects such as breakthrough bleedings (page 3584, second paragraph of section "Cervical and endometrial effects"). Although the patent only provided data for 10 mg and 20 mg dosages, it was apparent that the two had the same effect on bleedings, thus rendering it plausible that a 5 mg dosage would still be efficient for the same purpose; this was later confirmed by D18 (Figure 2A).

Auxiliary request VII: added subject-matter

The basis for the added feature "bleedings are stopped or reduced after the administration of ulipristal acetate for one menstrual cycle" was to be found in Figure 2 in combination with Example 1.

XI. The respondent's arguments, submitted in writing and in so far as relevant for the present decision, may be summarised as follows:

Main request and auxiliary requests I to III: inventive step

D3 was the closest prior art since it was concerned with a clinical trial on uterine fibrosis and there was no requirement to focus on bleedings out of all the symptoms. The patentees' argument that D3 was not suitable as the closest prior art disregarded the fact that the patent too was silent about bleedings, as apparent from Example 1 (paragraph [0056] of the patent; page 12, second paragraph of the application). The difference could only be that ulipristal acetate was used specifically for stopping bleedings in patients with uterine fibrosis (while D3 did not directly mention the symptom link), and the technical problem could be providing a new therapeutic use (as formulated by the appellant) or a new patient subgroup (as formulated by the opposition division), the two problems in fact being equivalent. The claimed solution was obvious, as correctly concluded by the opposition division, in view of D3 in combination with D15.

Auxiliary requests IV to VI: inventive step

Selecting a specific dose such as 5 mg was a random selection for which no effect had been shown or made plausible. Even if an effect was acknowledged, finding a dose was a routine task for the skilled person and there was always an incentive to provide a lower dose, in particular when a prior-art document (D8) already taught one such dose.

Auxiliary request VII: added subject-matter

The feature "after the administration of ulipristal acetate for one menstrual cycle" was disclosed in the application as filed only for Example 1, illustrated in Figure 2. Example 1, however, was disclosed with a number of further limiting features which were not present in claim 1, such as specific patients and 10 mg or 20 mg doses. The claimed subject-matter thus constituted an intermediate generalisation.

XII. The appellants requested in writing that the decision of the opposition division be set aside and that the patent be maintained as granted (main request) or, alternatively, according to any of auxiliary requests I to VII, all filed with the grounds of appeal.

The respondent requested in writing that the appeal be dismissed, that auxiliary requests VI and VII not be admitted into the proceedings and that documents D18 and D23 be "disregarded when assessing patentability of the opposed patent".

Reasons for the Decision

1. The appeal is admissible.

2. All parties had been duly summoned to oral proceedings but decided not to attend. In accordance with Rule 115(2) EPC the board decided to continue the oral proceedings in their absence.

   Moreover, pursuant to Article 15(3) RPBA the board was not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned. Accordingly, the absent parties were treated as relying only on their written submissions.

3. Admission of documents D18 and D23 and auxiliary requests VI and VII

3.1 In the communication pursuant to Article 15(1) RPBA, the board indicated that it saw no legal grounds to disregard documents D18 and D23 when assessing the patentability of the opposed patent, as requested by the respondent in its reply to the grounds of appeal. The board noted that the opposition division had admitted these documents into the proceedings, so they were *de facto* in the proceedings. The respondent did not provide any further submissions in this respect.

3.2 The board thus decided that the opposition division's decision to admit documents D18 and D23 into the proceedings was not to be reversed. In view of the outcome of the appeal, however, the board sees no need to justify this part of the decision.

3.3 Likewise, the board indicated in the communication pursuant to Article 15(1) RPBA that it was inclined to admit auxiliary requests VI and VII into the proceedings, contrary to the respondent's request in its reply to the grounds of appeal. Again there were no further submissions from the respondent in this respect, so the board decided to admit auxiliary requests VI and VII into the appeal proceedings. In view of the outcome of the appeal, however, the board sees no need to provide reasons for this part of the decision either.

4. Main request (claims as granted): inventive step

4.1 According to the patent application (page 1, first paragraph), the invention relates to a method for treating uterine fibroids (also called leiomyomata). The application (page 1, fourth paragraph) describes that the treatment depends on the symptoms, the tumour's location and size and the patient's age, being particularly recommended for those with excessive bleeding. The patent application proposes using ulipristal or one of its metabolites "for treating uterine fibroids, more particularly for reducing or stopping bleeding in a patient afflicted with uterine fibroids, reducing the size of uterine fibroids and/or reducing uterine volume" (page 5, last three lines). It is also taught that "ulipristal or a metabolite thereof alleviates symptoms of uterine fibroids, including bleeding, pelvic pain, pressure" (page 6, lines 5 to 6).

The closest prior art

4.2 Any document directed to treating uterine fibroids can be considered to represent suitable prior art as a

starting point in the problem-solution approach. Document D3, which undisputedly discloses treating symptomatic uterine fibroids with ulipristal acetate (in D3 designated as "CDB-2914", a former name for ulipristal according to the application on page 4, line 5), is one such document. D3 further teaches that, after 90 days of treatment, there was a 22% reduction in fibroid size and all treated women became amenorrheic.

4.3 The appellants argued that it was incorrect to select D3 as the closest prior art because it was not concerned with the technical problem addressed by the invention, namely alleviating bleedings as a symptom of uterine fibroids. D3 was a very short scientific report of a clinical trial aimed at determining whether administering ulipristal acetate would reduce fibroid size. Its teaching was deficient in that it did not disclose or suggest the patient subgroup of the invention, namely patients suffering from bleedings as a symptom of uterine fibroids. In D3 the patients were solely defined as being symptomatic; as evidenced by D1 and D15, however, bleedings were not a ubiquitous symptom in women afflicted with symptomatic fibroids, occurring in only 30% of the symptomatic patients.

4.4 The board notes that a document does not have to be directed to the same technical problem to be a suitable starting point for assessing inventive step; the document merely has to be related to a similar technical problem or to the same general problem – in this case treating uterine fibrosis. Moreover, it is irrelevant whether there might be better starting points than D3 because, for inventive step to be acknowledged, the subject-matter has to be inventive

from all suitable starting points. Clearly D3 is one such suitable starting point.

The objective technical problem

4.5 Claim 1 of the main request is a purpose-restricted claim pursuant to Article 54(5) EPC, in which the substance or composition is ulipristal acetate or its metabolites selected from the group consisting of CDB-3877, CDB-3963, CDB-3236 and CDB-4183, and the medical use is for reducing or stopping bleedings in a patient suffering from uterine fibroids. The board interprets this claim as being directed not to the treatment of uterine fibroids in general but rather to the treatment of a specific symptom of uterine fibroids, namely bleedings. Moreover, according to the application (page 1, lines 20 to 27) the aim of the uterine fibroid therapy in general is to stop or reduce "excessive uterine bleeding" (also called menorrhagia) associated with the uterine fibroids; it is not aimed at stopping or reducing (normal) menstrual bleeding.

4.6 The difference between D3 and claim 1 as granted is that D3 does not explicitly and unambiguously disclose treating bleeding in patients with uterine fibroids. The technical problem can thus be formulated as providing a treatment for bleedings in patients with uterine fibroids.

Obviousness of the claimed solution

4.7 The solution as claimed is using ulipristal acetate or its metabolites to treat bleedings in patients with fibroid-associated bleeding; the board is satisfied that this solution plausibly solves the technical problem (see also sections 4.11 and 4.12 below).

4.8 However, the claimed solution cannot be considered inventive. Document D3 clearly teaches that treatment with ulipristal acetate was efficacious in that it reduced fibroid size and stopped bleeding in all patients (regardless of whether or not these patients had fibroid-associated bleeding). It was common knowledge, as reflected in the patent (e.g. paragraph [0004]) and evidenced by e.g. D15 (page 434, section "Symptomatology") and D1 (page 2, section "Clinical Features"), that bleeding was a major clinical manifestation in patients with symptomatic uterine fibroids. Hence the skilled person would be prompted to use the treatment disclosed in D3 for uterine fibroid patients also as a general treatment for a specific symptom of fibroids, namely bleeding, and would have a more than reasonable expectation that said treatment would be suitable for reducing or stopping such bleeding since D3 teaches that the treatment was successful for all treated patients.

4.9 The appellants essentially argued that D3 neither disclosed nor suggested that ulipristal acetate was effective in reducing or stopping bleedings in patients suffering from uterine fibrosis. The treatment's reported effect on reducing fibroid size would not provide the skilled person with a reasonable expectation of success because it was known from the prior art that there was no positive correlation between fibroid size and bleedings.

4.10 The board disagrees with the appellants' arguments. D3 is a short meeting abstract with little experimental detail, but it clearly teaches that symptomatic uterine fibroid patients were treated with ulipristal and the treatment was efficacious in that it reduced fibroid

size and led to amenorrhea in all patients. As concluded above, the teaching of D3 alone is thus sufficient to render the claimed subject-matter obvious, so it is irrelevant that the patent may provide more information than D3. Moreover, contrary to the appellants' arguments, Example 1 of the patent did not select only patients with bleedings: "Inclusion criteria included regular cycles and contraceptive use, and symptomatic fibroids as defined by ACOG practice bulletin 1994: - Excessive uterine bleeding (...); or anemia due to acute or chronic blood loss; - or pelvic discomfort caused by leiomyomata, either acute or severe or chronic lower abdominal or low back pressure or bladder pressure with urinary frequency not due to urinary tract infection" (paragraph [0054]). The same inclusion criteria appear to have also been used in D3, which states: "Inclusion criteria included symptomatic fibroids as defined by ACOG, regular cycles and contraceptive use" (first sentence of section "Materials and Methods"). The only difference is that D3 does not explicitly state what the symptoms are. Moreover, Example 1 of the patent does not clearly define a subgroup of patients with bleedings either because, as mentioned above, the inclusion criteria also covered other symptoms and groups were not split according to symptoms.

4.11 Lastly, Example 1 of the patent reports the following results (paragraph [0055]): "During the three month study interval, the total fibroid volume increased by 6% among those receiving PLC [placebo]; those receiving 10 mg and 20 mg [of ulipristal/CDB-2914] demonstrated a 36% and 21% reduction in fibroid volume, respectively (see Figure 1). When the two CDB-2914 groups were combined in comparison to PLC, there was a significant reduction in total fibroid volume after three months of

therapy (PLC: 6%; CDB-2914: -29%; p=0.01). (...) Women receiving PLC had monthly menses throughout the study interval. On the contrary, there was only a single episode of menstrual bleeding occurring in a subject receiving 10 mg; no woman receiving 20 mg had any bleeding (see Figure 2). When compared to PLC, CDB-2914 was associated with a significant reduction in menses with evidence of a dose-dependent effect (p<0.001)". These results are very similar to those obtained in D3: "When evaluating the size of the largest fibroid within groups, PL [placebo] had an average increase of 16% (...) while CDB had a 22% reduction (...). All CDB patients became amenorrheic" (section "Results"); "Compared to PL, CDB-2914 at 10 or 20 mg daily significantly reduced the size of fibroids by 22% after 90 days, and induced amenorrhea" (section "Conclusions"; compare with paragraph [0056] of the patent).

4.12 As such, neither Example 1 of the patent nor D3 allows a conclusion to be drawn on whether the therapy has a direct effect on bleedings; however, both teach that the therapy was effective against uterine fibrosis, thus rendering such an effect plausible since treatment of a disease is generally expected to alleviate its symptoms.

4.13 The appellants also argued that the amenorrhea disclosed in D3 as a treatment result would correspond solely to the cessation of physiological menstruation and not to any effect on pathological bleeding as a symptom of uterine fibroids, which, as explained in D23, section 4, were two different clinical situations. While the board agrees with this view, it notes that in any case Example 1 of the patent also only refers to the therapy having an effect on bleeding in the context

of menstrual bleeding, as is apparent from the above-cited passages of Example 1. Hence, if the teaching of document D3 were to be considered deficient in this respect, the same would be true of the experimental data disclosed in the patent.

4.14 Lastly, as to the argument that at the priority date the skilled person would not have expected a reduction in fibroid size to have had any effect on bleedings, the following is noted. As taught in the patent, the recommended therapeutic approach to uterine fibroids for menorrhagia and excessive bleeding was in fact aimed at reducing tumour size (paragraph [0004]), the other option being surgical extirpation by hysterectomy or myomectomy (paragraph [0005]). Document D19 does report a negative correlation between leiomyoma size and bleeding (Figure 2), but the bleedings are in the context of menstrual blood losses and not of leiomyoma-associated bleedings in general, as in the patent. Even though D23 (section 4) teaches that "the pathogenesis of leiomyoma-related menorrhagia is complex and not fully understood" and that there might be no direct correlation with tumour size and location, it also confirms (section 5) that GnRH agonists were the "first-line treatment" for managing leiomyoma-related bleedings; as explained in paragraph [0004] of the patent, GnRH agonists were used to reduce tumour size.

4.15 Claim 1 is thus considered to lack inventive step. The main request is not allowable under Article 100(a) EPC.

5. Auxiliary requests I, II and III: inventive step

5.1 Claim 1 of these requests differs from claim 1 of the main request in that the following features were added: "wherein bleedings are a symptom of uterine fibroids in

said patient" (auxiliary requests I and III) and "at a daily dosage of 5 mg to 15 mg" (auxiliary requests II and III).

5.2 The appellants did not provide any arguments as to how these features were meant to contribute to inventive step, stating simply that these requests were inventive for the same reasons as given for the main request.

5.3 The board considers the feature "wherein bleedings are a symptom of uterine fibroids in said patient" to be redundant in the context of the claimed subject-matter and notes that document D3 discloses a 10 mg dosage, thus falling within the claimed range. Hence, the board considers that the added features do not contribute to inventive step.

5.4 The claims of auxiliary requests I, II and III are thus considered to lack inventive step. These requests are not allowable for lack of compliance with Article 56 EPC.

6. Auxiliary requests IV, V and VI: inventive step

6.1 The feature "at a daily dosage of 5 mg" was added to claim 1 of auxiliary requests IV, V and VI, and auxiliary requests V and VI further include the feature "wherein bleedings are a symptom of uterine fibroids in said patient". In auxiliary request VI the metabolites of ulipristal acetate were deleted and it was specified that administration was by oral route.

6.2 Document D3 does not disclose the dosage recited in these requests. However, the board agrees with the opposition division's reasoning that finding a lower dosage which still has a therapeutic effect on a given

disease was a routine task for the skilled person. The board agrees with the appellants that although the patent only provided data for 10 mg and 20 mg dosages, it was apparent that the two had the same effect on bleedings, thus rendering it plausible that a 5 mg dosage would still be efficient for the same purpose, as later confirmed in D18. It is, however, noted that the same data is also present in D3, as set out above in section 4.11.

6.3 As to the appellants' arguments that D8 would teach away from using ulipristal acetate at a 5 mg dosage because of potential adverse effects, the board notes that D8 is concerned with another use of the compound, namely for contraception, where different effects are to be achieved. Hence, the skilled person would be aware that the teaching of D8 might not be applicable to the different clinical setting to which the invention relates, and would not be deterred from testing dosages which might not be optimal in the clinical context of D8.

6.4 The appellants have not indicated how deleting the metabolites and limiting administration to the oral route in claim 1 of auxiliary request VI are meant to contribute to inventive step. The board notes that D3 in fact discloses using ulipristal acetate and not any of the now-deleted metabolites. Moreover, the patent application teaches the oral route as just one route among other "convenient" routes (page 6, lines 26 to 27), and the oral route in fact appears to be the usual route of administration for ulipristal acetate (e.g. D8).

6.5 Hence the board considers that the claims of auxiliary requests IV to VI are directed to subject-matter which

lacks inventive step. Auxiliary requests IV, V and VI are not allowable for lack of compliance with Article 56 EPC.

7. Auxiliary request VII: added subject-matter

7.1 In this request, claim 1 has been amended by adding *inter alia* the following feature: "wherein (...) bleedings are stopped or reduced after the administration of ulipristal acetate for one menstrual cycle". The appellants indicated Figure 2 and Example 1 of the application as filed as the basis for this amendment.

7.2 The board does not consider the passages indicated by the appellants to constitute an adequate basis for the added feature and fails to see any other basis in the application as filed. Firstly, the board agrees with the respondent that any effect on bleeding stopping after one menstrual cycle shown in Figure 2 is in the context of specific dosages, namely 10 mg and 20 mg, which are not part of the claim. As such, this amendment results in an intermediate generalisation for which there is no basis in the application as filed. Additionally, the board notes that while the present claim refers to bleedings in general, the passage in Example 1 describing Figure 2 (paragraph [0055]) refers specifically to menstrual bleeding: "Additional analyses evaluated treatment-related differences in menstrual function. Women receiving PLC had monthly menses throughout the study interval. On the contrary, there was only a single episode of menstrual bleeding occurring in a subject receiving 10 mg; no woman receiving 20 mg had any bleeding (see Figure 2)". As such, neither Figure 2 nor Example 1 can provide a basis for the added feature.

7.3 Claim 1 of auxiliary request VII thus has no basis in the application as filed. Auxiliary request VII is not allowable for lack of compliance with Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated