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**Datasheet for the decision
of 26 May 2026**

Case Number: T 0358/25 - 3.3.07

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Language of the proceedings: EN

Title of invention:
PHARMACEUTICAL DELIVERY SYSTEMS FOR HYDROPHOBIC DRUGS AND
COMPOSITIONS COMPRISING SAME

Patent Proprietor:
Besins Healthcare Luxembourg SARL

Opponent:
Aera A/S

Headword:
Delivery systems for hydrophobic drugs / BESINS HEALTHCARE

Relevant legal provisions:

RPBA 2020 Art. 12(2), 12(3), 12(4)

EPC Art. 56

Keyword:

Statement of grounds of appeal - party's complete appeal case
(yes)

Admittance of arguments - (yes)

Admittance of requests - auxiliary requests 1 to 11 (yes)

Inventive step - main request and auxiliary requests 1 to 11
(no)



Beschwerdekammern

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Case Number: T 0358/25 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 26 May 2026

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted/
electronically transmitted on 19 December 2024
concerning maintenance of the European Patent
No. 2985026 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: J. Lécaillon
L. Basterreix

Summary of Facts and Submissions

- I. European patent 2 985 026 (hereinafter "the patent") was granted on the basis of 4 claims. The independent claim of the patent as granted related to a pharmaceutical composition comprising testosterone palmitate or a testosterone ester, two or more lipid components and components that can modulate testosterone absorption.
- II. An opposition was filed against the patent on the grounds that its subject-matter lacked inventive step, it was not sufficiently disclosed and its subject-matter extended beyond the content of the divisional, parent and grandparent applications as originally filed.
- III. The opposition division took the decision that, on the basis of auxiliary request 3 filed on 28 September 2023, the patent met the requirements of the EPC. This decision was based on the patent as granted (main request) and three auxiliary requests filed on 28 September 2023.

Auxiliary request 3 contained 2 claims. The independent claim of auxiliary request 3 read as follows:

"1. A pharmaceutical composition for oral delivery comprising testosterone palmitate or a testosterone ester; and two or more lipid components, at least the first of which comprises a hydrophilic surfactant selected from Cremaphor RH40™ (polyoxyethylene (40) hydrogenated castor oil) & Etocas 40™ (polyoxyethylene (40) castor oil);

at least the second of which comprises a lipophilic surfactant that provides for the controlled release of testosterone palmitate or a testosterone ester thereof selected from:

fatty acids (C6-C24);
mono- and/or di-glycerides of fatty acids;
acetic, succinic, lactic, citric and/or tartaric esters of mono- and/or di-glycerides of fatty acids;
propylene glycol mono- and/or di-esters of fatty acids;
polyglycerol esters of fatty acids;
acid and ester ethoxylates formed by reacting ethylene oxide with fatty acids or glycerol esters of fatty acids (HLB<10);
sorbitan esters of fatty acids;
transesterification products of natural or hydrogenated vegetable oil triglyceride and a polyalkylene polyol (HLB<10);
alcohol ethoxylates (HLB<10); and
Pluronics,

wherein the formulation contains components that can modulate testosterone absorption selected from natural and synthetic inhibitors of 5 α -reductase and inhibitors of cytochrome P450 isozyme CYP3A4,
wherein the inhibitor of 5 α -reductase is borage oil,
and
wherein the inhibitor of cytochrome P450 isozyme CYP3A4 is peppermint oil."

IV. The decision of the opposition division, posted on 19 December 2024, cited *inter alia* the following documents:

D1: WO 97/40823

D3: F.D. Gunstone, *Gamma-linoleic Acid in Encyclopedia of Food Sciences and Nutrition*, 2003, 2nd Ed, p. 2308-2311

D4: Liang *et al.*, *Journal of Investigative Dermatology*, 109, 1997, p. 152-157

D5: Dresser *et al.*, *Clinical Pharmacology & Therapeutics*, 72, 2002, p. 247-255

D7: CFR Title 21, Part 182, Section 182.20 (U.S. FDA), 1 April 2004 - accessed via the Wayback Machine.

V. The opposition division decided in particular as follows:

- (a) The claims of the main request (patent as granted) and of auxiliary requests 1 and 2 did not meet the requirements of Articles 123(2) and 76((1) EPC.
- (b) Auxiliary request 3 met the requirements of Rule 80 and Articles 123(2) and 76(1) EPC.
- (c) The ground of opposition under Article 100(b) was not admitted into the opposition proceedings.
- (d) The subject-matter of the claims of auxiliary request 3 involved an inventive step. D1 represented the closest prior art. The claimed compositions differed from those of D1 in that they contained borage oil or peppermint oil. In the absence of an appropriate substantiation of a technical effect resulting from these distinguishing features, the objective technical problem resided in the provision of alternative pharmaceutical compositions comprising a testosterone ester, a hydrophilic surfactant and a lipophilic surfactant that provided controlled

release of a testosterone ester. The relevant prior art did not suggest to replace miglyol in the compositions of D1 with either borage oil or peppermint oil.

- VI. The opponent (appellant) lodged an appeal against the above decision of the opposition division.
- VII. With its reply to the appellant's statement setting out the grounds of appeal the patent proprietor (respondent) defended its case on the basis of a main request corresponding to the auxiliary request 3 maintained by the opposition division, and alternatively on the basis of auxiliary requests 1 to 11 filed therewith.

The content of the claims upon which the present decision is based can be illustrated as follows:

The content of claim 1 of the main request was already provided above (see III.).

Claim 1 of auxiliary request 1 corresponded to claim 1 of the main request wherein the feature "for oral delivery" was deleted.

Claim 1 of auxiliary request 2 corresponded to claim 1 of the main request wherein the feature "that can modulate testosterone absorption" was deleted.

Claim 1 of auxiliary request 3 corresponded to claim 1 of the main request wherein the features "for oral delivery" and "that can modulate testosterone absorption" were deleted.

Claim 1 of auxiliary request 4 read as follows:

"1. A pharmaceutical composition for oral delivery comprising testosterone palmitate or a testosterone ester; and two or more lipid components, at least the first of which comprises a hydrophilic surfactant selected from Cremaphor RH40™ (polyoxyethylene (40) hydrogenated castor oil) & Etocas 40™ (polyoxyethylene (40) castor oil); at least the second of which comprises a lipophilic surfactant that provides for the controlled release of testosterone palmitate or a testosterone ester thereof selected from:

fatty acids (C6-C24);
mono- and/or di-glycerides of fatty acids;
acetic, succinic, lactic, citric and/or tartaric esters of mono- and/or di-glycerides of fatty acids;
propylene glycol mono- and/or di-esters of fatty acids;
polyglycerol esters of fatty acids;
acid and ester ethoxylates formed by reacting ethylene oxide with fatty acids or glycerol esters of fatty acids (HLB<10);
sorbitan esters of fatty acids;
transesterification products of natural or hydrogenated vegetable oil triglyceride and a polyalkylene polyol (HLB<10);
alcohol ethoxylates (HLB<10); and
Pluronics,

wherein the formulation contains borage oil and peppermint oil."

Claim 1 of auxiliary request 5 corresponded to claim 1 of auxiliary request 4 wherein the feature "for oral delivery" was deleted.

Claim 1 of auxiliary request 6 read as follows:

"1. A pharmaceutical composition for oral delivery comprising testosterone palmitate or a testosterone ester; and two or more lipid components, at least the first of which comprises a hydrophilic surfactant selected from Cremaphor RH40™ (polyoxyethylene (40) hydrogenated castor oil) & Etocas 40™ (polyoxyethylene (40) castor oil); at least the second of which comprises a lipophilic surfactant that provides for the controlled release of testosterone palmitate or a testosterone ester thereof selected from:

fatty acids (C6-C24);
mono- and/or di-glycerides of fatty acids;
acetic, succinic, lactic, citric and/or tartaric esters of mono- and/or di-glycerides of fatty acids;
propylene glycol mono- and/or di-esters of fatty acids;
polyglycerol esters of fatty acids;
acid and ester ethoxylates formed by reacting ethylene oxide with fatty acids or glycerol esters of fatty acids (HLB<10);
sorbitan esters of fatty acids;
transesterification products of natural or hydrogenated vegetable oil triglyceride and a polyalkylene polyol (HLB<10);
alcohol ethoxylates (HLB<10); and
Pluronics,

wherein the formulation contains components that can modulate testosterone absorption selected from inhibitors of cytochrome P450 isozyme CYP3A4, wherein the inhibitor of cytochrome P450 isozyme CYP3A4 is peppermint oil."

Claim 1 of auxiliary request 7 corresponded to claim 1 of auxiliary request 6 wherein the feature "for oral delivery" was deleted.

Claim 1 of auxiliary request 8 corresponded to claim 1 of auxiliary request 6 wherein the feature "that can modulate testosterone absorption" was deleted.

Claim 1 of auxiliary request 9 corresponded to claim 1 of auxiliary request 6 wherein the features "for oral delivery" and "that can modulate testosterone absorption" were deleted.

Claim 1 of auxiliary request 10 read as follows:

"1. A pharmaceutical composition for oral delivery comprising testosterone palmitate or a testosterone ester; and two or more lipid components, at least the first of which comprises a hydrophilic surfactant selected from Cremaphor RH40™ (polyoxyethylene (40) hydrogenated castor oil) & Etocas 40™ (polyoxyethylene (40) castor oil); at least the second of which comprises a lipophilic surfactant that provides for the controlled release of testosterone palmitate or a testosterone ester thereof selected from:

fatty acids (C6-C24);
mono- and/or di-glycerides of fatty acids;

acetic, succinic, lactic, citric and/or tartaric esters of mono- and/or di-glycerides of fatty acids;
propylene glycol mono- and/or di-esters of fatty acids;
polyglycerol esters of fatty acids;
acid and ester ethoxylates formed by reacting ethylene oxide with fatty acids or glycerol esters of fatty acids (HLB<10);
sorbitan esters of fatty acids;
transesterification products of natural or hydrogenated vegetable oil triglyceride and a polyalkylene polyol (HLB<10);
alcohol ethoxylates (HLB<10); and
Pluronics,

wherein the formulation contains peppermint oil."

Claim 1 of auxiliary request 11 corresponded to claim 1 of auxiliary request 10 wherein the feature "for oral delivery" was deleted.

VIII. The following items of evidence were filed by the parties during the appeal proceedings:

(a) Document filed by the appellant with their statement of grounds of appeal:

D8: WO 2004/087052 A2

(b) Document filed by the respondent with the reply to the statement of grounds of appeal:

D9: Schmidt *et al.*, Natural Product Communications, Vol. 4 (8), 2009, 1107-112

- IX. On 4 February 2026 the Board issued a communication pursuant to Article 15(1) RPBA and provided their preliminary opinion.
- X. By letter dated 18 February 2026, the respondent announced that they would not be attending the oral proceedings scheduled to take place before the Board on 16 June 2026.
- XI. The oral proceedings were cancelled.
- XII. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

They further requested that auxiliary requests 1 to 11 not be admitted into the appeal proceedings.

- XIII. The respondent requested that the appeal be dismissed, *i.e.* the patent be maintained as amended during the first instance proceedings (new main request), or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 11 filed with the reply to the statement of grounds of appeal.

They further requested that the parts of the appellant's statement of grounds of appeal, which either do not address the decision or address aspects of the decision not adversely affecting the appellant, be dismissed.

- XIV. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) The arguments contained in the statement of grounds of appeal objected to by the respondent were not to be dismissed. They addressed:

- (i) either requests and reasons forming part of the impugned decision and hence part of the appeal proceedings (Article 12(2) RPBA),
 - (ii) or lower-ranked requests submitted and a *priori* maintained in opposition proceedings and which could be expected to be relied upon by the respondent during the appeal proceedings, so that the requirement of Article 12(3) RPBA regarding the submission of a complete case with the statement of grounds justified their discussion.
- (b) The main request did not meet the requirements of Article 56 EPC. The claimed subject-matter differed from the closest prior art D1 in that the composition contained borage oil and/or peppermint oil. No technical effect had been demonstrated for this distinguishing feature. The objective technical problem resided therefore in the provision of an alternative composition. D1 already disclosed the use of digestible oils such as miglyol in the formulations of testosterone esters (see D1 pages 5 to 6). As acknowledged in the impugned decision, borage oil and peppermint oil were known to be digestible oils (see D3 and D7). The skilled person looking for an alternative composition would thus have considered the use of alternative digestible oils to those of D1. The skilled person would therefore have either added borage oil and/or peppermint oil to the compositions of D1 or substituted miglyol with these oils. The functional definitions mentioned in claim 1 of the main request did not render the claimed subject-matter inventive. γ -linoleic acid

was known to be a main component of borage oil, which was itself known to be an inhibitor of 5- α -reductase (see D3, "Background" section and D4, Abstract). Peppermint oil was known as an inhibitor of CYP3A4 (see D5, "Conclusions" section of the Abstract).

- (c) Auxiliary requests 1 to 11 should not be admitted into the appeal proceedings (Article 12(4) RPBA). Auxiliary requests 1 to 11 constituted unjustified amendments to the respondent's case and were not convergent. In particular, auxiliary requests 6 to 9 were less limited than higher-ranking requests, and no reordering had been attempted during the opposition proceedings. Moreover, auxiliary requests 6 to 11 were not substantiated, as the respondent had failed to indicate the basis for the amendments or to explain why these, in combination with document D9, would lead to a different assessment of inventive step.
- (d) Auxiliary requests 1 to 11 did not meet the requirements of the EPC. In particular, auxiliary requests 6 to 11 differed from the main request and auxiliary requests 1 to 5 in that the presence of borage oil in the composition had been deleted. The arguments provided in support of the addition of (or substitution of miglyol with) peppermint oil to the compositions of D1 detailed for the main request applied *mutatis mutandis*. Also the submission of D9 relating to the structure of peppermint oil did not affect the reasoning regarding the obviousness of an addition of peppermint oil.

XV. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

(a) The following arguments provided in the statement of grounds of appeal not addressing the decision or addressing specific issues not adversely affecting the appellant were to be dismissed:

- arguments relating to the main request and auxiliary requests 1 and 2 on file in the opposition proceedings,
- the statement that the arguments for auxiliary request 3 on file in the opposition proceedings are "basically the same" as for the main request without an indication of which specific arguments were meant,
- arguments regarding auxiliary requests 4 to 9 on file in the opposition proceedings which did not form part of the impugned decision, and
- arguments relating to the non-validity of the priority claimed.

(b) The main request fulfilled the requirements of Article 56 EPC. The claimed subject-matter differed from the closest prior art D1 in that the composition contained borage oil and/or peppermint oil. Even if it had not been experimentally shown, the properties of borage oil and peppermint oil were mentioned and credible from the prior art. Not any digestible oil could be used as an alternative to the specific ones disclosed in D1. Peppermint oil differed structurally from the oils disclosed in D1, as evidenced by D9 (see Table 1), and its use was therefore not obvious. Similarly, borage oil was not an arbitrary alternative, since its selection was based on the presence of γ -linolenic acid rather than its triglyceride nature.

Furthermore, both oils possessed intrinsic properties relevant to the invention, independently of experimental data. The absence of working examples did not necessarily imply that the claimed subject-matter merely provided an alternative, since the alleged functions were supported by the prior art and were credible. The claims related to compositions comprising testosterone esters and additional components, including the oils, rather than to the oils as such. None of documents D3, D4 or D5 suggested the use of borage oil or peppermint oil in the context of testosterone ester compositions.

- (c) Auxiliary requests 1 to 11 were to be admitted into the appeal proceedings. They were filed with the reply to the statement of grounds of appeal, which contained an explanation of which objections these auxiliary requests were meant to overcome.

- (d) Auxiliary requests 1 to 11 involved an inventive step for the same reasons as the main request. In particular, auxiliary requests 6 to 11 were limited to peppermint oil. The difference between this oil and the digestible triglyceride-based oils as defined in D1 was substantiated by D9.

Reasons for the Decision

- 1. Admittance of arguments
 - 1.1 The respondent requested that the following appellant's arguments provided in the statement of grounds of appeal and relevant for the present decision be dismissed:

- (a) arguments relating to the main request and auxiliary requests 1 and 2 on file in the opposition proceedings,
- (b) the statement that the arguments for auxiliary request 3 on file in the opposition proceedings were "basically the same" as for the main request without an indication of which specific arguments are meant,
- (c) arguments regarding auxiliary requests 4 to 9 on file in the opposition proceedings which did not form part of the impugned decision, and
- (d) arguments relating to the non-validity of the priority claimed.

1.2 Regarding item (a), as stated by the appellant, the reasoning of the opposition division for the then main request and auxiliary requests 1 and 2 forms part of the impugned decision and hence of the appeal proceedings according to Article 12(2) RPBA. The issue of whether the outcome of the decision for the corresponding requests adversely affected the appellant or not is not relevant in defining the basis of the appeal proceedings. The appellant's right to discuss individual arguments of the impugned decision remains unaffected.

1.3 The same applies *mutatis mutandis* to item (d) above.

1.4 Regarding item (b) above, since the claims of the present main request (auxiliary request 3 in the opposition proceedings) are partially based on the claims of the previous main request and auxiliary requests 1 and 2 discussed in the impugned decision, several issues are common to all the requests. In such cases, it is usual to address said issues for the highest request and not reiterate the complete argument

for the subsequent lower-ranking request(s) but merely refer to the previous reasoning.

The Board further observes that, in the present case, the appellant did not only generally refer to the arguments regarding the higher-ranking requests of the opposition proceedings when discussing the amendments of auxiliary request 3 underlying the impugned decision (present main request) but provided detailed arguments why the reasoning of the opposition division regarding the additional modification to claim 1 of said auxiliary request 3 would in their opinion be wrong (see point 6.2 on pages 8 to 9 of the statement of grounds of appeal). Subsequently, the appellant concluded that, as a consequence, the same reasoning as for the higher-ranking requests still applied.

- 1.5 Finally, item (c) above concerns auxiliary requests submitted and *a priori* maintained during the opposition proceedings but not discussed in the impugned decision since a higher-ranking request was found allowable.

While these auxiliary requests do indeed not automatically form part of the appeal proceedings according to Article 12(2) RPBA, it may nevertheless be expected that the respondent may resubmit them with its reply to the statement of grounds of appeal and that they might be admitted into the appeal proceedings. This scenario actually occurred in the present case since auxiliary requests 7, 4, 8, 5 and 9 of the opposition proceedings were resubmitted as auxiliary requests 1 to 5 with the reply to the statement of grounds of appeal.

According to Article 12(3) RPBA, the statement of grounds of appeal shall contain a party's complete

appeal case, which explains the anticipation of the appellant in providing arguments for auxiliary requests 4 to 9 of the opposition proceedings. Furthermore, the respondent did not contest that the objections against those auxiliary requests were already raised during the opposition proceedings.

- 1.6 Accordingly, there is no reason to exclude the arguments (a) to (d) listed above from the appeal proceedings.

Main request

2. Inventive step

2.1 Closest prior art and distinguishing features

2.1.1 The present main request relates to a pharmaceutical composition for oral delivery comprising:

- testosterone palmitate or a testosterone ester, and
- two or more lipid components wherein at least the first of which comprises a hydrophilic surfactant and at least the second of which comprises of lipophilic surfactant, and
- further components selected from borage oil and peppermint oil.

According to paragraph [0006] of the patent, the purpose of the claimed subject-matter is a composition that provides enhanced bioavailability of testosterone or an ester thereof *in vivo* over an extended period of time.

- 2.1.2 Both parties agreed with the impugned decision that D1 represented the closest prior art. The Board sees no reason to differ.

D1 discloses pharmaceutical compositions of testosterone and testosterone ester containing *inter alia* a lipophilic surfactant, a hydrophilic surfactant and a digestible oil (see e.g. claim 13 and examples 21 to 38). In particular, the compositions of examples 21 to 23, 27 to 29 and 33 to 35 are liquid compositions of testosterone undecanoate comprising a hydrophilic surfactant and a lipophilic surfactant according to present claim 1. According to page 3 lines 20 to 24, particular combinations of digestible oils and mixtures of lipophilic and hydrophilic surfactants provide a carrier system which is capable of solubilising significant amounts of hydrophobic drugs. Moreover, as indicated on page 4 lines 24 to 27 the formulations of D1 have been designed to disperse immediately in aqueous environments such as gastrointestinal tract, forming fine emulsions or microemulsions.

2.1.3 The parties also agreed with the impugned decision that the claimed compositions differed from those of D1 in the presence of borage and/or peppermint oil. The Board adheres thereto.

2.2 Technical effect and objective technical problem

2.2.1 As stated in the impugned decision, there is no evidence on file of any technical effect over the closest prior art compositions attributable to the distinguishing features.

2.2.2 In this context, the Board notes that, in addition to the absence of any comparison with the closest prior art compositions, the only examples of compositions containing borage and peppermint oil of the patent (see formulations 70, 70B, 71, 71A and 71B in table 4 and

Figures 14 and 15) are labelled as "reference examples only" in the sub-heading between paragraphs [0093] and [0094]. It follows that even the alleged purpose of the patent, namely the provision of controlled/extended release formulations, does not appear to have been experimentally shown as achieved.

- 2.2.3 The respondent argued that even if not experimentally shown, the properties of borage oil and peppermint oil were credible from the prior art and should be taken into account.
- 2.2.4 The Board notes however, that the respondent did not identify a specific technical effect attributable to the use of the claimed oils in addition to or instead of the digestible oils of D1, in particular the miglyol oil of the examples thereof.
- 2.2.5 The respondent did further not formulate any specific objective technical problem. They essentially argued that the two claimed oils were special compared to those described in D1 and did not represent an arbitrary alternative since their functions as mentioned in paragraphs [0091] and [0092] of the patent were important for the present invention.
- 2.2.6 The Board considers that the fact that properties, which may be known from the prior art, influencing testosterone (esters) absorption and metabolism are mentioned in the patent for the claimed oils does not mean that an effect of said oils in the final claimed compositions, let alone compared to the closest prior art compositions containing different further ingredients, has been rendered credible.

2.2.7 The Board therefore concurs with the appellant that the objective technical problem should be formulated as the provision of an alternative pharmaceutical composition of testosterone or testosterone ester.

2.3 Obviousness

2.3.1 As noted in the impugned decision, D1 does not disclose borage oil or peppermint oil. However, the Board considers that, in the absence of any demonstrated technical effect associated with borage oil or peppermint oil (and also not miglyol), the addition of, or substitution of miglyol with, further known digestible oils including borage oil (see e.g. D3, "Background" section) or peppermint oil (see e.g. D7) would have represented one of several equally obvious alternatives. In this context, the structural differences between the digestible oils of present claim 1 (in particular regarding peppermint oil, as shown in Table 1 of D9) and the digestible oils defined in D1 would not have deterred the skilled person from considering these alternatives since no particular effect linked to those structural differences was established.

2.3.2 Moreover, the argument of the opposition division and the respondent based on a purposive choice of borage oil and peppermint oil in view of their properties in modulating testosterone absorption is not convincing. As submitted by the respondent (with reference to paragraphs [0091] and [0092] of the patent) and by the appellant (with reference to the abstracts of D4 and D5), the properties of borage oil and peppermint oil as inhibitors of 5 α -reductase and CYP3A4 respectively were known at the priority date. Hence, the purported "special" and "non-arbitrary" character of these oils

had been known to the skilled person at the priority date. Their use in the compositions of D1 on the basis of these known properties, in the absence of any further particular effect, cannot provide inventiveness.

2.3.3 As a result, the Board concurs with the appellant that it would have been obvious for the skilled person to add borage oil and/or peppermint oil to (or substitute them for the digestible oils in) the compositions of D1.

2.4 Consequently, the main request does not meet the requirements of Article 56 EPC.

Auxiliary requests 1 to 11

3. Admittance

3.1 The appellant requested that auxiliary requests 1 to 11 not be admitted into the appeal proceedings. According to the appellant, these requests would not be structured in a convergent manner. Furthermore, the respondent would have failed to provide a substantiation as to the reasons why auxiliary requests 6 to 11 would overcome the objection of lack of inventive step.

3.2 The appellant's arguments regarding the lack of substantiation of auxiliary requests 6 to 11 (Article 12(3) RPBA) are not convincing. The respondent's reply to the statement of grounds of appeal contains an explanation of which objections auxiliary requests 1 to 11 are meant to overcome.

3.3 The Board further notes that, although auxiliary requests 1 to 11 are indeed not strictly convergent, merely four different amendments were performed and a clear structure within the various auxiliary requests can be identified. When, as in the present case, several objections under different grounds of opposition and concerning different features of the claims were raised, the proprietor should be entitled to defend themselves, including by filing auxiliary requests. In such circumstances, it cannot be expected that these requests will always be strictly converging.

3.4 Moreover, the amendments performed (all deletions) are not complex and are suitable to address at least some of the issues on file and their submission is not against procedural economy.

3.5 As a result, auxiliary requests 1 to 11 are admitted in the appeal proceedings (Article 12(4) RPBA)

4. Inventive step

4.1 Starting from claim 1 of the main request, the following deletions were made individually and in various combinations thereof in auxiliary requests 1 to 11:

- deletion of "for oral delivery",
- deletion of the functional definition "that can modulate testosterone absorption",
- deletion of the functional definitions "selected from natural and synthetic inhibitors of 5 α -reductase and inhibitors of cytochrome P450 isozyme CYP4A" and "wherein the inhibitor of 5 α -reductase is" and "wherein the inhibitor of cytochrome P450 isozyme CYP4A is", and

- deletion of the functional definitions "natural and synthetic inhibitors of 5 α -reductase" and "wherein the inhibitor of 5 α -reductase is borage oil".

- 4.2 None of these deletions introduce any further difference versus the closest prior art D1. Consequently the reasoning developed for the main request applies *mutatis mutandis* to the present auxiliary requests 1 to 11.
- 4.3 The respondent did not provide any specific argument on how these features would overcome the finding of lack of inventiveness for the main request. In particular, not only borage oil was considered an obvious feature but also peppermint oil. The limitation of the subject-matter claimed in auxiliary requests 6 to 11 to peppermint oil cannot therefore render it inventive.
- 4.4 Therefore, auxiliary requests 1 to 11 do not meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The patent is revoked.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated