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**Datasheet for the decision  
of 14 January 2026**

**Case Number:** T 1179/23 - 3.3.07

**Application Number:** 13704974.8

**Publication Number:** 2817000

**IPC:** A61K9/16, A61K9/50,  
A61K31/4439, A61P7/02,  
A61K9/14, A61K9/48

**Language of the proceedings:** EN

**Title of invention:**

ORAL PHARMACEUTICAL COMPOSITIONS OF DABIGATRAN ETEXILATE

**Patent Proprietor:**

TOWA PHARMACEUTICAL EUROPE, S.L.

**Opponents:**

Aera A/S  
Hamm&Wittkopp Patentanwälte PartmbB

**Headword:**

Compositions of dabigatran etexilate / TOWA PHARMACEUTICAL

**Relevant legal provisions:**

RPBA 2020 Art. 12(4), 12(3), 12(5), 12(6), 13(2)  
EPC Art. 56, 123(2)  
EPC R. 139

**Keyword:**

Late-filed evidence - admittance in appeal proceedings (yes)  
Requests filed during appeal proceedings - admitted (yes)  
Request for continuation in writing - rejected  
Validity of priority date (yes)  
Amendments - correction of obvious errors (no)  
Inventive step - main request and auxiliary requests 1 and 2  
(no), auxiliary requests 3 and 15 (yes)

**Decisions cited:**

T 0709/17, T 1654/22, T 0702/22, T 0212/22, T 2163/22,  
T 0686/91



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Case Number: T 1179/23 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 14 January 2026**

**Appellant:** Aera A/S  
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**Representative:** Hamm&Wittkopp Patentanwälte PartmbB  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
20 June 2023 concerning maintenance of the  
European Patent No. 2817000 in amended form.**

**Composition of the Board:**

**Chairman**           A. Usuelli  
**Members:**         J. Lécaillon  
                      Y. Podbielski

## **Summary of Facts and Submissions**

- I. European patent 2 817 000 (hereinafter "the patent") was granted on the basis of 6 claims defining a composition comprising dabigatran etexilate mesylate and a process for its preparation.
- II. Three oppositions were filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as originally filed.
- III. Opponent 1 withdrew its opposition on 1 December 2022.
- IV. The opposition division took the decision that the patent met the requirements of the EPC on the basis of the amended main request filed on 27 September 2022. The amended main request contained 6 claims. Claims 1 and 2 read as follows:

"1. A pharmaceutical composition for oral administration comprising a mixture of at least two types of particles wherein a) the first type of particles comprise dabigatran etexilate mesylate and which is free from acids; and b) the second type of particles comprise at least one pharmaceutically acceptable organic acid and wherein at least one type of particles are coated with a protective coating layer and wherein the composition comprises from 0.01 wt% to 90 wt% of dabigatran etexilate mesylate, based on the total weight of the composition."

2. "A process for the preparation of a composition according to claim 1 comprising the step of mixing said first type of particles and said second type of particles with at least one pharmaceutically acceptable excipient."

V. The decision of the opposition division, posted on 20 June 2023, cited *inter alia* the following documents:

D1: WO 2012/001156

D13: The EMA's "CHMP ASSESSMENT REPORT" for Pradaxa (2008)

D14: CN102793699 A

D19: "Pharmaceutics - The Science of Dosage Form Design", Aulton, M.E., Churchill Livingstone, 2002, Ed. 2, pages 247-248

D23: T 0709/17

D24: Experimental evidence "Dabigatran capsules - API blend prepared by direct blending, Batch 047-31-01"

D29: PatBase search results, 2 September 2022

D31: PatBase search results, 22 March 2023

D33: Comparative dissolution results with respect to Pradaxa®

D35: Experimental evidence versus D1

D36: Banakar, Umesh V., "Pharmaceutical Dissolution Testing", Ed. Marcel Dekker, Vol. 49, 1992, pages 263-272

D37: "Pharmaceutics - The Science of Dosage Form Design" Aulton, M.E., Churchill Livingstone, 2002, Ed. 2, pages 456-459

D38: "Pharmazeutische Technologie", 1997, 5<sup>th</sup> Edition, K.H. Bauer *et al.*, Gustav Fischer Verlag, pages 337-349

VI. The opposition division decided in particular as follows:

- (a) The main request met the requirements of Articles 123(2) and 123(3) EPC. In particular, the correction of an obvious error in paragraph [0088] of the description was allowable according to Rule 139 EPC.
- (b) The main request fulfilled the requirements of Article 83 EPC.
- (c) The priority date was validly claimed. Consequently, D14 did not constitute prior art relevant for the issues of novelty and inventive step.
- (d) The subject-matter of the claims of the main request was novel over D1. It furthermore involved an inventive step starting from the multilayered one-particle compositions C1 or C2 of D1, which represented the closest prior art. In particular, the skilled person would not have expected to achieve a faster dissolution at early time points when preparing a two-particle composition generally suggested on page 14 of D1.

VII. The opponents 2 and 3 (appellant-opponent 2 and appellant-opponent 3) lodged an appeal against the above decision of the opposition division.

VIII. With its reply to the appellants-opponents' statement setting out the grounds of appeal the patent proprietor (respondent) defended its case on the basis of the patent as amended during the opposition proceedings as the main request, and on the basis of auxiliary

requests 1 to 23, wherein auxiliary requests 1, 2, 6 to 8, 12 to 14 and 18 to 20 corresponded to auxiliary requests 1 to 5 and 12 to 17 filed during the opposition proceedings on 27 September 2022. Auxiliary requests 12 to 23 corresponded to the main and auxiliary requests 1 to 11 with an amendment to the description (amended paragraph [0088]).

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

Claim 1 of the main request was already illustrated under point IV. above.

Claim 1 of auxiliary request 1 read as follows:

"1. A pharmaceutical composition for oral administration comprising a mixture of at least two types of particles wherein a) the first type of particles comprise dabigatran etexilate mesylate and which is free from acids; and b) the second type of particles comprise at least one pharmaceutically acceptable organic acid, wherein at least one type of particles are coated with a protective coating layer, wherein the composition comprises from 0.01 wt% to 90 wt% of dabigatran etexilate mesylate, based on the total weight of the composition, and wherein said organic acid is selected from the group consisting of tartaric acid, fumaric acid, succinic acid, citric acid, and malic acid."

Claim 1 of auxiliary request 2 corresponds to claim 1 of auxiliary request 1 wherein the last feature defining the organic acid read "wherein said organic acid is tartaric acid".

Claim 1 of auxiliary request 3 read as follows:

"1. A pharmaceutical composition for oral administration comprising a mixture of at least two types of particles wherein a) the first type of particles comprise dabigatran etexilate mesylate and which is free from acids; and b) the second type of particles comprise at least one pharmaceutically acceptable organic acid, wherein at least one type of particles are coated with a protective coating layer, wherein the composition comprises from 0.01 wt% to 90 wt% of dabigatran etexilate mesylate, based on the total weight of the composition, and wherein the composition is in the form of a capsule."

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

(a) Documents filed by appellant-opponent 2 (D42 and D43) and appellant-opponent 3 (D44) with their statements setting out the grounds of appeal:

D42: Felton and McGinity, Drug Development and Industrial Pharmacy, 28(3), 225-243 (2002)

D43: Document from the Argentinian Ministry of Health - Ministro de Salud, Secretaria de Politicas, Regulacion e Institutos. Disposicion No 3261, 5 April 2017

D44: Experimental data - Dabigatran Etexilate Capsules 75 mg

(b) Documents filed by the respondent with its reply to the statement setting out the grounds of appeal:

D45: Experimental evidence comparing the dissolution profile of the composition according to Example C1 of document D1 with a composition according to the Patent.

- (c) Documents filed by appellant-opponent 3 with their letters dated 2 May 2024 (D46) and 9 January 2026 (D48):

D46: IP.com Journal, 31 May 2005, IPCOM000125373D, cited in D23,

D48: Copy of the "Beschluss of the Landgericht München I" in the matter "21 O 15509/24" dated 30 December 2025.

- (d) Document filed by the respondent with their letter dated 25 September 2025:

D47: WO 2012/104419 A1.

- X. Oral proceedings were held before the Board on 14 January 2026.
- XI. The appellants-opponents 2 and 3 requested that the decision under appeal be set aside and that the patent be revoked. Appellant-opponent 3 further requested that auxiliary requests 1 to 23 not be admitted into the appeal proceedings.
- XII. The respondent requested that the appeals be dismissed and the patent be maintained as amended during the opposition proceedings (main request), and as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1 to 23 submitted with the reply to the statements setting out the grounds of appeal (hereinafter "reply to the appeals").

The respondent further requested that documents D42 to D44 not be admitted into the appeal proceedings, and that D45 be admitted.

The respondent also requested in writing in their letter dated 9 January 2026 that document D48 and the accompanying arguments of appellant-opponent 3 dated 9 January 2026 not be admitted.

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

(a) Admittance of items of evidence

D42 to D44 were to be admitted into the appeal proceedings. They were filed with the statements of grounds of appeal in direct response to the impugned decision and/or documents filed within the Rule 116 EPC time period. D48 was also to be admitted. This order of the "Landgericht München I" dated 30 December 2025 could not have been filed earlier.

(b) Validity of the priority

According to appellant-opponent 2, the priority date claimed was not valid, because the corresponding priority document did not directly and unambiguously disclose dabigatran etexilate mesylate (DEM) containing particles "free from acid". Consequently D14 represented valid prior art for the assessment of novelty and inventive step.

(c) Inventive step - Main request and auxiliary requests 1 and 2

The simple mixture of particles disclosed in the sentence of page 14 lines 7 to 8 of D1 represented the closest prior art embodiment. However, if the multilayered one-particle formulations C1 and C2 of D1 were considered instead, the claimed compositions: either (i) did not differ from two-particle compositions when claim 1 was interpreted as done by appellant-opponent 2, or (ii) differed therefrom in that the organic acid and DEM were contained in two separated particles. The effect of faster dissolution of DEM at early time points had not been appropriately substantiated, let alone over the whole scope of the claims as shown in D44. Moreover, according to appellant-opponent 3, the effect of a faster dissolution rate at early time points was in any case to be disregarded because it was not technically useful. The objective technical problem resided therefore in the provision of an alternative composition of DEM. A simple mixture of two separate particles was already suggested on page 14 of D1. The subject-matter of claim 1 of the main request did thus not involve an inventive step. The same reasoning applied *mutatis mutandis* to auxiliary requests 1 and 2.

(d) Admittance of auxiliary requests 3 and 15

According to appellant-opponent 3, auxiliary requests 3 and 15 were not to be admitted into the appeal proceedings. The respondent failed to provide details as to how auxiliary requests 3 and 15 would overcome the objections of lack of inventive step. Moreover, these requests should have been filed already during the opposition proceedings. Furthermore, the admittance

of these requests in reply to D44 would place appellant-opponent 3 in a worse position than if they had not filed D44.

Finally, the admittance of said auxiliary requests at this stage would render it very difficult to react thereto. As a result, if auxiliary requests 3 and 15 were admitted into the proceedings, the proceedings should be continued in writing.

(e) Inventive step - Auxiliary requests 3 and 15

The technical effect alleged by the respondent had not been appropriately substantiated or was even to be disregarded for the reasons provided for the main request. Furthermore, according to appellant-opponent 2, despite the limitation of the subject-matter of claim 1 to capsule formulations, the alleged technical effect was still not credible over the whole scope of the claims in view of the influence of the capsule material on dissolution. Hence, the objective technical problem remained the provision of an alternative DEM composition. Nevertheless, should the technical effect be taken into account and the objective technical problem be considered as the provision of a DEM formulation with faster dissolution at early time points, the present solution would still be obvious. The skilled person would have been motivated to prepare a two-particle composition by the sentence on page 14 lines 7 to 8 of D1. The resulting effect on dissolution would have been expected. Furthermore, if required, the skilled person would have added a (super)disintegrant to the composition to further increase the dissolution based on common general knowledge. The subject-matter of claim 1 of auxiliary request 3 and 15 did thus not involve an inventive step.

(f) Correction of an error

The correction of the error in the prior art reference in paragraph [0088] of the patent was not obvious, since it was not immediately evident that nothing else could have been meant as a correction (see D31).

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

(a) Admittance of items of evidence

D42 to D44 should not be admitted into the appeal proceedings because they should have already been filed in the opposition proceedings. Furthermore no reasons for the admittance of D44 had been provided in the appellant-opponent 3's statement of grounds of appeal. D48 was not to be admitted because it was extremely late filed, so that there was insufficient time for the respondent to react thereto.

(b) Validity of the priority

The description of the priority document P1, when taken as a whole (in particular pages 4 to 5 and the examples), directly and unambiguously, though implicitly, disclosed that the DEM containing particles should be free from acid. The claimed priority date was therefore validly claimed and D14 did not represent relevant prior art for the assessment of novelty and inventive step.

(c) Inventive step - Main request and auxiliary requests 1 and 2

The multilayered one-particle formulations C1 and C2 of D1 represented the closest prior art embodiment. The claimed compositions differed therefrom in that the organic acid and DEM were contained in two separated particles. The data provided in example 3 of the patent, D24, D35 and D45 substantiated that the resulting technical effect was a faster dissolution of DEM at early time points. The objective technical problem resided therefore in the provision of a formulation having faster dissolution at early time points. None of the cited prior art documents disclosed or suggested that the separation of DEM and the acid in two different particles would provide such an effect. The subject-matter of claim 1 of the main request was therefore inventive. The same reasoning applied *mutatis mutandis* to auxiliary requests 1 and 2.

(d) Admittance of auxiliary requests 3 and 15

Auxiliary requests 3 and 15 were filed with the reply to the appeals. The amendment performed in claim 1 (*i.e.* limitation to a capsule) was not complex and directly addressed the inventive step objection based on D44, filed with appellant-opponent 3's statement of grounds of appeal. These requests were therefore to be admitted into the appeal proceedings.

(e) Inventive step - auxiliary requests 3 and 15

In view of the limitation of the subject-matter of claim 1 to capsule formulations, the technical effect was credible over the whole scope of the claims. The same reasoning as developed for the main request

applied *mutatis mutandis*. The claimed subject-matter involved an inventive step.

(f) Correction of an error

The error in the reference to the prior art in paragraph [0088] of the patent was obvious as well as its correction, as substantiated by the PatBase search results (D29).

### **Reasons for the Decision**

1. Admittance of items of evidence
  - 1.1 D42 to D44 were submitted by the appellants-opponents with the statements of grounds of appeal. Their admittance is to be decided on the basis of Article 12(4) RPBA.
  - 1.2 D43
    - 1.2.1 D43 was filed by appellant-opponent 2 to show the quantitative composition of Pradaxa<sup>®</sup> used in D33.
    - 1.2.2 The respondent argued that D43 should have been filed together with D33, *i.e.* already during the opposition proceedings. During the oral proceedings, the respondent further stated that D43, being a document from the Argentinian ministry of health, could not provide evidence of the composition of Pradaxa available in the USA, as used in D33.
    - 1.2.3 The Board observes that D43 represents a direct response to the decision of the opposition division considering the data of D33 deficient due to the lack of information regarding the quantitative composition

of the tested compositions (see page 22, first paragraph, of the impugned decision). D43 therefore addresses the issue on file. The question of whether D43 actually provides convincing evidence of the fact alleged by appellant-opponent 2 is not to be assessed when examining the admittance of the document. Furthermore, D43 was filed as early as possible in the appeal proceedings and the content of D43 referred to is not complex.

1.2.4 Hence, D43 is admitted into the appeal proceedings (Article 12(4) RPBA).

1.3 D44

1.3.1 According to appellant-opponent 3, D44 provides further evidence of their argument already raised during the first instance proceedings based on common general knowledge (*inter alia* as evidenced in D19) that the dissolution rate of dabigatran etexilate mesylate (DEM) would be determined by the time needed for the capsule mass to disintegrate.

1.3.2 The respondent argued that appellant-opponent 3 did not provide reasons for the admittance of D44 in their statement of grounds of appeal and that D44 should have been submitted during the opposition proceedings (Article 12(6) RPBA).

1.3.3 The Board observes that appellant-opponent 3 discussed in detail D44 and the experimental results provided therein in their statement of the grounds of appeal. Even if not explicitly stated, it is implicit that this document was filed in response to the decision of the opposition division finding that D35 substantiated the effect alleged by the respondent. The Board sees

furthermore no compulsory reason why D44 should have already been filed during the opposition proceedings. This document therefore addresses issues that led to the impugned decision. Its content is furthermore not complex and it was filed as early as possible in the appeal proceedings.

1.3.4 As a result, D44 is admitted into the appeal proceedings (Article 12(4) RPBA).

1.4 D42

D42 was filed by appellant-opponent 2 in response to D35 filed by the respondent (then patent proprietor) during the opposition proceedings with their submission pursuant to Rule 116 EPC two months before the oral proceedings (filed as "D32"). D42 was meant to support the argument that talc and titanium dioxide may influence the dissolution rate of the compositions tested in D35. The issue of admittance of D42 is moot in view of the Board's finding that no technical effect can be acknowledged based on D35 (see point 4.3.3 below).

1.5 No objections against the admittance of D45 to D47 were raised. D45 was filed in direct response to the statements of the grounds of appeal. D46 is the closest prior art in the case underlying the decision cited as D23 in the present proceedings. D47 corresponds to the document cited as D2 in the decision T 1654/22 cited by appellant-opponent 2. These documents are admitted into the appeal proceedings.

1.6 D48 was submitted by appellant-opponent 3 with their letter dated 9 January 2026. Its admittance is to be decided on the basis of Article 13(2) RPBA.

- 1.6.1 D48 is a copy of the order of the "Landgericht München I" dated 30 December 2025 to stay the infringement proceedings initiated by the patentee until the Board has decided on the present appeal. In this order the court indicated that it was likely that the Board would revoke the patent in suit in the version corresponding to the present main request for lack of inventive step. In this context, the court shared the view of appellant-opponent 3 that a faster dissolution at early time points was not useful.
- 1.6.2 The respondent argued that the submission of the copy of the decision on 9 January 2026, *i.e.* a few days before the oral proceedings, was extremely late and that there was insufficient time for the respondent to review and react to the submitted order and accompanying arguments of appellant-opponent 3.
- 1.6.3 The Board observes that, while not being bound by decisions of national courts, such decisions are nevertheless taken into account by the boards.

Furthermore, D48 is dated 30 December 2025 and was hence filed very shortly after its issuance. The Board is therefore satisfied that there are exceptional circumstances justifying the filing of D48 only at a late stage.

The argument of the respondent regarding the lack of time to react to the submission of D48 is not convincing. The respondent actually initiated the infringement proceedings in front of the "Landgericht München I" and must necessarily have been aware of the content of D48, even before its submission by appellant-opponent 3. Moreover, neither D48 nor the

accompanying letter of appellant-opponent 3 of 9 January 2026 provide any new argument. The objection that the alleged effect would not be technically useful had indeed already been raised by appellant-opponent 3 in their statement of grounds of appeal (see pages 18 to 20).

- 1.6.4 It follows that D48 is admitted into the appeal proceedings (Article 13(2) RPBA).

*Main request*

2. Priority

- 2.1 Appellant - opponent 2 objected that the priority date claimed was not valid. According to them, the corresponding document P1 (IN 461/MUM/2012, filing date 21 February 2012) would not directly and unambiguously disclose DEM containing particles "free from acid" as defined in present claim 1.

- 2.2 As mentioned by the respondent, the priority document P1 teaches that DEM is acid sensitive (see page 4, first paragraph) and that there are stability issues when the active is in close contact with an organic acid without any special steps to separate the two from each other (see page 4, last paragraphs). According to the following paragraphs of P1, in the compositions of the invention, special steps were taken to separate the active agent, including DEM, from the organic acid to prepare stable compositions (see page 5, third and fourth paragraph, of P1), namely by preparing two separate types of particles "wherein a) first type of particles comprise one or more direct thrombin inhibitors; b) the second type of particles comprise at least one pharmaceutically acceptable organic acid".

The Board therefore shares the opinion of the opposition division that the skilled person would directly and unambiguously understand from these passages of P1, although not explicitly stated therein, that the DEM containing particles should be free from acid. Contrary to the view of appellant-opponent 2 view, this represents indeed the direct and inevitable consequence of separating the active from the acid in two different particles.

Furthermore, as argued by the respondent, the methods of preparation of the compositions of the invention (see pages 13 to 14 of P1) and the examples of P1 provide a further pointer, if required, to the absence of acid in the DEM containing particles.

2.3 Appellant-opponent 2 brought forward that the passages of P1 cited by the respondent would not support their case because they:

- (i) related to the background of the invention but not to the disclosure of the actual invention,
- (ii) were limited to organic acids without any basis to extrapolate to any type of acids, and/or
- (iii) concerned
  - "direct thrombin inhibitors" in general but not specifically DEM, or
  - "dabigatran etexilate" but not specifically the mesylate salt thereof.

Regarding point (i), the Board considers that the fact that this information is provided in the background section of P1 is irrelevant. As argued by the respondent, P1 has to be considered as a whole and this

passage discloses a general teaching which led to the invention.

Concerning point (ii), the last paragraph on page 4 does indeed mention only organic acids. However, as explained in the impugned decision, this paragraph concerns the background art mentioned therein which related to organic acids. Furthermore, the first paragraph on page 4 generally indicates the acid sensitivity of DEM. The skilled person would therefore have directly and unambiguously understood that the absence of any acids was required for the preparation of stable compositions.

Regarding point (iii), the compositions of the invention disclosed on page 5 of P1 do indeed contain any "direct thrombin inhibitors". However, when considering P1 as a whole, it is directly and unambiguously derivable that DEM is the preferred active ingredient because DEM is the only specific active described in detail (see pages 3 and 4) and used in all the examples of P1.

- 2.3.1 Appellant-opponent 2 further insisted on the fact that, while the acid sensitivity of DEM was indeed identified in P1, the provided solution thereto was the provision of DEM and acid in two separate particles (see page 5, second and third paragraphs) wherein a protective coating layer on at least one of said particles was merely optional. According to appellant-opponent 2, present claim 1 required that the DEM particles did not contain any acid in any amount. Appellant-opponent 2 was further of the opinion that, in compositions as defined in P1 containing a mixture of DEM-particles and acid-particles none of which being coated with a protective layer, both types of particles could be in

contact. It resulted from this contact that DEM particles would no longer be free of acid.

The Board disagrees with this conclusion. First of all, a skilled person would not consider a mere contact between both particles as resulting in the DEM-particle *per se* containing acid, even in very small amounts. Moreover, a contact between DEM and acid, let alone one resulting in some undefined manner in the DEM-particle allegedly containing acid, remains purely speculative, even for an embodiment without any protective layer.

2.4 Consequently, the priority date of P1 is validly claimed (Article 87 EPC).

### 3. Novelty

In the appeal proceedings, only novelty over D14 had been objected to (by appellant-opponent 2). Since the priority date is considered validly claimed, D14 (CN patent application published on 28 November 2012, *i.e.* during the priority year) does not constitute relevant prior art for the assessment of patentability of the present patent. The novelty objection is therefore no longer relevant.

### 4. Inventive step

#### 4.1 Closest prior art

4.1.1 The present main request relates to a pharmaceutical composition for oral administration comprising DEM and an organic acid wherein DEM and the organic acid are present in two types of particles, wherein at least the DEM comprising particles are free of acid and wherein

at least one type of particles is coated with a protective layer.

4.1.2 It was undisputed that D1 represented the closest prior art document. D1 is a patent application disclosing pharmaceutical oral dosage forms of DEM, in particular multilayered compositions (see page 6, paragraph below "summary of the invention"; page 8, second full paragraph; claim 1; examples). The parties however disagreed as to the choice of the starting point within D1.

4.1.3 The respondent was of the opinion that the simple mixture mentioned on page 14 lines 7 to 8 of D1 did not represent a realistic starting point and that this choice would build on hindsight knowledge of the present patent. Instead the multilayered compositions of examples C1 and C2 represented the closest prior art embodiments.

4.1.4 Both appellants-opponents considered that the embodiment mentioned in the sentence on page 14 lines 7 to 8 of D1 relating to a simple mixture of isolated tartaric acid pellets and dabigatran represented the closest prior art embodiment.

In particular, the appellants-opponents argued during the oral proceedings that simple mixtures of the isolated pellets with DEM were disclosed as an equal alternative to the multilayered pellets in D1 serving the same purpose and for which the same effects were to be expected.

4.1.5 The Board disagrees and is of the opinion that the skilled person reading the sentence on page 14 lines 7 to 8 of D1 understands it as speculative and as not

referring to an actual concrete realisation of simple mixtures. The reasons are the following:

- As underlined by the opposition division and the respondent, the "simple mixture" used by the appellants-opponents as a starting point is disclosed at one single occurrence in D1 in one single sentence, namely "Alternatively, the simple mixture of isolated pellets and dabigatran is filled into capsules or sachets" (see page 14 lines 7-8). There is no further mention or description of this "simple mixture" in the entire document.
  
- The Board agrees with the appellants-opponents that the core of the invention in D1 resides in the provision of "isolated pellets" being round and without satellites. According to D1 (see pages 7 to 9), these isolated pellets are prepared from starter pellets made of a core (sugar spherical cores or tartaric acid pellets) and an acid coating, which are further coated with an isolating layer. As however argued by the appellants-opponents themselves during the oral proceedings, the absence of satellites aims at avoiding contact between the acid layer and the DEM layer after coating of the isolated pellets with the DEM layer (see D1, page 7 last paragraph to page 8 first paragraph, as well as the paragraph bridging pages 8 and 9). The advantage of round isolated pellets without satellites is therefore disclosed in D1 in the context of multilayered compositions. Hence the core of the invention is indeed the "isolated pellets" but for the further preparation of multilayered compositions. Indeed claim 1, the "summary of the invention" (see page 6 of D1) and the examples of final compositions exclusively

concern multilayered pellets containing tartaric acid and the active ingredient in different layers.

- Furthermore, the main purpose of D1 is to provide a pharmaceutical composition of DEM which is stable and achieves dissolution of DEM. It is undisputed that the separation of the layers serves the purpose of avoiding DEM degradation upon contact with the acid during storage. D1 further teaches that the function of the acid layer is to provide an acidic micro environment when the solid dosage form disintegrates to facilitate DEM dissolution (see paragraph bridging pages 10 to 11). There is however no evidence why the skilled person would consider that a similar acidic micro environment would be achieved with a simple mixture of two particles as mentioned on page 14 of D1, which does not impose a requirement of vicinity of DEM and the acid. In this regard, the Board notes that, while D1 refers in the background section to compositions based on multilayered pellets containing DEM and the acid in different layers, it provides no indication of the existence of compositions in which DEM and the organic acid are in different discrete particles. In this context, the explanation of appellant-opponent 3 based on a capsule plug containing the mixture of isolated tartaric acid pellets and DEM remains speculative in the present specific case, in particular since sachets are envisaged as alternative to capsules on page 14 of D1.

4.1.6 The Board observes that the present case differs from those underlying the decisions T 702/22, T 212/22 and T 2163/22 cited by appellant-opponent 2, in which a comparative tablet was chosen as closest prior art, in

that said tablet was a well-described and actually prepared composition.

The present case also differs from the one underlying decision T 1654/22 relied upon by the appellants-opponents. In this earlier case a non-exemplified embodiment was considered to represent the closest prior art embodiment. However, the chosen embodiment was disclosed as a clear embodiment of the invention considered to be non-speculative (see reasons 1.1.6).

4.1.7 It follows that, in the Board's view, the "simple mixture" mentioned on page 14 of D1 does not represent a realistic starting point. The starting point for assessing inventive step starting from D1 is therefore the multilayered compositions of examples C1 or C2.

4.2 Distinguishing feature

4.2.1 In the written proceedings, appellant-opponent 2 argued that there would be no distinguishing feature between the multilayered compositions of D1 and the claimed composition. They indeed considered that since the DEM layer was applied by spraying a DEM suspension (*i.e.* containing undissolved DEM particles) onto the isolated pellets of D1, isolated DEM particles would be deposited on the top of the protective layer of the isolated pellets. Accordingly the composition comprised two types of particles.

4.2.2 This argument is not convincing. As brought forward by the respondent, even if the situation would be as described by appellant-opponent 2, the resulting product would be regarded as a composite particle *i.e.* still as one type of particle, whereas present claim 1 requires the presence of at least two types of

particles. Moreover, as argued by the respondent, the preparation examples of the compositions C1 and C2 of D1 do not provide any indication supporting that DEM would be deposited as physically independent particles onto the surface of the isolated pellets and Figure 1 of D1 clearly indicates a dabigatran layer. The skilled person would therefore not understand the disclosure of D1 as encompassing "two types of particles" as defined in present claim 1.

4.2.3 Thus, the claimed compositions differ from the layered compositions C1 or C2 of D1 in that the organic acid and DEM are contained in two different particles rather than in a single particle.

4.3 Technical effect

4.3.1 The respondent brought forward that the technical effect resulting from the distinguishing feature was a faster dissolution of DEM at early time points, as substantiated in example 3 of the patent, D24, D35 and D45.

4.3.2 The appellants-opponents contested that this technical effect had been shown as directly linked to the distinguishing feature and that it would have been made credible over the whole scope of the claims. They based their arguments on D35 and D45 as well as D33 and D44.

4.3.3 The Board observes that example 3 of the patent, D24 and D35 are not suitable to substantiate a technical effect over the closest prior art mainly because the compared compositions differ from each other in several features and not only in the above identified distinguishing feature. Furthermore, D33, even when taking D43 into account, cannot convincingly

substantiate that the observed difference in dissolution rate is directly linked to the present distinguishing feature, because the full quantitative composition of the two-particle composition tested in D33 is missing (the amounts of other excipients beyond tartaric acid are not specified).

- 4.3.4 Hence, the only documents providing appropriate comparisons are D45 and D44.

*D45 - submitted by the respondent*

- 4.3.5 The compositions tested in D45 differ from each other only in the structure of the formulations, namely multilayered one-particle composition according to D1 (see table 1, page 2 of D45) and two-particle composition according to the present claims (see table 1, page 3 of D45). The tested compositions contain otherwise exactly the same excipients in exactly the same amounts.

In this context, the mention of isopropanol in the API blend in the compositions according to the invention was a point of discussion between the parties during the written proceedings. In their letter dated 12 March 2025, the respondent stated that the amount of isopropanol added to the blend was 0. This was indeed derivable from the process of preparation of the blend, which mentions a simple mixing of the components and no wet granulation (see flowchart in section 2.2.2 of D45). It follows that, as explained by the respondent, isopropanol is neither present in the multilayered one-particle composition according to D1 (because it is evaporated upon drying) nor in the two-particle composition according to the present claim 1.

4.3.6 The results of D45 substantiate that the two-particle composition according to present claim 1 shows a faster dissolution at early time points than the composition according to D1 (see Table 4 and Figure 1 on page 6 of D45).

4.3.7 Appellant-opponent 2 considered that the data of D45 could not be relied upon because:

- the asymptotic values for both compositions were different despite having exactly the same excipients merely arranged differently,
- the comparative composition without outer coating in D45 dissolved at a higher final percentage than the same comparative composition with an outer coating in D35, and
- the data for the composition according to the claims in D45 was merely "recycled" from the experiment of D35, so that D45 was not a truly comparative experiment.

4.3.8 These arguments are not convincing.

As argued by the respondent, the difference in the asymptotic values is attributable to normal experimental variations obtained when carrying out such experiments. Furthermore, the differences in final asymptotic values are minor compared to the differences in dissolution at early time points, which are therefore significant and which represent the actual technical effect invoked by the respondent.

The same consideration applies to the differences between the two different comparative compositions tested in D45 and D35.

The respondent stated in the letter dated 12 March 2025 (see paragraph [27]) that the tests disclosed in D35 and D45 had been carried out with the same experimental conditions and equipment. The parameter of dissolution is a composition-specific parameter which will remain unchanged (within measurement errors) when tested under the same conditions and with the same equipment. Hence, there was no need to repeat the experiment with the same two-particle compositions when preparing D45.

4.3.9 Appellant-opponent 3 considered that:

- the hydroxypropyl cellulose (HPC) contained in the two-particle composition of D45 would cause faster dissolution rates due to its hydrophilic nature and the "plug" appearance imparted to the mixture through encapsulation,
- the presence of talc in the two-particle composition of D45 would cause faster dissolution rates due to its ability to reduce cohesiveness of the particles in the blend, and
- the "location" or "exposure" of the excipients HPC and talc in the composition according to the invention and the comparative composition represented an additional difference.

Similarly, appellant-opponent 2 argued during the oral proceedings that the hydrophobicity of the various surfaces exposed to the exterior environment in the composition according to D1 and the one according to the present claims, in view of the respective amounts of talc and HPC, would also represent an additional difference.

According to the appellants-opponents, the effect observed in D45 could therefore not be directly attributed to the identified distinguishing feature

over the closest prior art, namely DEM and the acid being in two separate particles.

4.3.10 The Board is not convinced by these arguments.

The Board observes that HPC is present in both tested compositions (*i.e.* in the API blend of the two-particle composition and in the API layer in the one-particle composition) in the same amount. The same applies to talc (present in each of the acid or DEM particles or layers in the same amounts). This is a requirement for an appropriate comparison. Any effect purely due to the presence of HPC or talc should thus not be the reason for any difference in behaviour between the two compositions.

Furthermore, appellant-opponent 3 only referred to textbooks passages on the dissolution of capsules (D19, D36 to D38) in support of this argument, without any specific evidence that the suggested mechanism would indeed occur with HPC or talc, in the amounts presently used and for the present composition. In particular, the experiments submitted in D44 do not appear to confirm a specific effect of HPC or talc. Indeed when HPC is replaced by the same amount of talc (Trial III), the same dissolution rate as with HPC is observed (Trial II) and when talc is replaced by the same amount of HPC, a slower dissolution rate at early time points is obtained.

Should however any of the effects alleged by the appellants-opponents indeed occur, they could only be due to the "location" or "exposure" of the excipients. This would still directly result from the structure of the formulations (multilayered one-particle versus two-particle), *i.e.* the distinguishing feature, when filled

in capsules. The comparative tests provided by the respondent were therefore construed in a reasonable and appropriate manner and are meaningful.

*Usefulness of the alleged technical effect*

- 4.3.11 Appellant-opponent 3 argued that, even if a faster dissolution rate at early time points would be recognised, it would not have any technical usefulness in the context of the invention. According to appellant-opponent 3, as indicated in D13 (see page 9 lines 20 to 24), a faster dissolution at early time points has no impact on oral bioavailability of DEM.
- 4.3.12 This lack of influence on bioavailability was not disputed by the respondent, who argued that the advantage imparted by the faster dissolution at early time points would be the provision of more formulation options, for example in terms of more excipient options.
- 4.3.13 The Board considers that a faster dissolution at early time points has in essence a technical character. Furthermore, as underlined by the respondent, D13 also states that "the selection of excipients and their corresponding levels was based on *in vitro* dissolution, stability, and *in vivo* bioavailability studies using various prototype formulations" (see page 9, fourth paragraph). Hence, the faster dissolution at early time points imparted to the claimed compositions by their two-particle structure may indeed allow to select for example excipients which otherwise would not provide sufficiently fast dissolution. This *per se* represents a useful property for the presently claimed subject-matter, which relates to a product as such. Restricting the usefulness of a technical effect of a product to

its impact on bioavailability, *i.e.* on its medical use, would in the present case not be reasonable when assessing the inventiveness of the product *per se*.

In this context the Board observes that, contrary to the opinion of appellant-opponent 3, this conclusion is not in contradiction with decision T 686/91. T 686/91 states that "all technical advantages which a person skilled in the art would reasonably consider useful and which have been credibly achieved with respect to the relevant closest state of the art have to be taken into account." (see page 9 last paragraph, emphasis added). In said earlier case, the Board actually concluded that the technical effect was to be taken into account since the opponent in said case "did not give any good reason why a skilled person would not have considered" that the effect at issue would be "a desirable advantage". For the reasons detailed above, this situation applies to the present case.

*D44 - submitted by appellant-opponent 3*

4.3.14 D44 provides a comparison of two-particle compositions according to D45 wherein HPC or talc were replaced by the same amounts of each other. The obtained data do not raise doubts as to the technical effect over the closest prior art observed in D45. This effect is actually confirmed in D44 (compare Trial I and Trial II) for the reasons provided above (see 4.3.10, third paragraph).

4.3.15 However, D44 also provides comparisons between the dissolution of the compositions of D45 filled into the capsules, and the dissolution of the same compositions but wherein the capsules were opened (see Trial I and Trial II). When the capsules were opened before

performing the dissolution test, no significant difference in dissolution rate between the composition according to D1 and the one according to present claim 1 is observed.

4.3.16 The Board observes that claim 1 is not limited to compositions being filled in capsules. It follows that the effect observed in D45 does not appear to necessarily occur for any possible final dosage form comprising the mixture according to claim 1, e.g. for sachets. This finding was not disputed by the respondent at the oral proceedings. The Board therefore considers that the faster dissolution rate at early time points has not been convincingly substantiated over the whole scope of present claim 1. This technical effect cannot therefore be considered for the formulation of the objective technical problem.

#### 4.4 Objective technical problem

As a result, starting from the multilayered compositions C1 or C2 of D1, the objective technical problem to be solved can only be defined as the provision of an alternative DEM formulation.

#### 4.5 Obviousness

In the absence of any particular effect, the provision of a simple mixture of two separate particles as mere alternative is suggested by D1 itself (see page 14 lines 7-8). During the oral proceedings, the respondent did not dispute this conclusion if the objective technical problem was formulated as in point 4.4 above.

- 4.6 Therefore, the subject-matter of claim 1 of the main request does not meet the requirements of Article 56 EPC.

*Auxiliary requests 1 and 2*

5. Inventive step

Claims 1 of auxiliary requests 1 and 2 differ from claim 1 of the main request in that the organic acid was limited to a list of specific acids including tartaric acid (auxiliary request 1) and to specifically tartaric acid (auxiliary request 2). Since the compositions C1 and C2 of D1 contain tartaric acid in the acid containing pellets (see isolated pellets B1 and starter pellets A8), these features do not represent distinguishing features over the closest prior art. The reasoning provided for the main request therefore applies *mutatis mutandis* to auxiliary requests 1 and 2. It follows that auxiliary requests 1 and 2 do not meet the requirements of Article 56 EPC.

*Admittance of auxiliary requests 3 and 15*

6. Admittance

6.1 Claim 1 of auxiliary requests 3 and 15 corresponds to claim 1 of the main request wherein the dosage form was limited to a capsule. Appellant-opponent 3 requested that auxiliary requests 3 and 15 submitted with the reply to the appeals not be admitted.

6.2 Contrary to the opinion of appellant-opponent 3, the respondent clearly identified the amendments performed in auxiliary requests 3 and 15 and provided reasons for their submissions (see paragraph 24 of the reply to the

appeals), in accordance with Article 12(4), second paragraph, RPBA.

- 6.3 During the oral proceedings, appellant-opponent 3 argued that these requests should have been filed already during the opposition proceedings (Article 12(6) RPBA). According to appellant-opponent 3, they already raised the issue of the disintegration of the capsule mass being the limiting factor for the dissolution of formulations according to the claims, so that the present amendment should have already been performed in response to this argument and could not have been triggered by the submission of D44.
- 6.4 This argument is not convincing. As argued by the respondent, D44 was filed in response to the finding of the opposition division in the impugned decision that D35 demonstrated the effect of faster dissolution at early time points. The Board considers that there was no compulsory reason for the respondent to submit present auxiliary requests 3 and 15 during the opposition proceedings, since the opposition division found the argument of appellant-opponent 3 not convincing.
- 6.5 Finally, appellant-opponent 3 argued that the liberation of an active ingredient from a capsule was very complex. In appellant-opponent 3's view the admittance of these auxiliary requests in response to the submission by appellant-opponent 3 of D44 would put said appellant in a worse position than if D44 had not been filed. Furthermore, the admittance of said auxiliary requests at this stage would render it very difficult for appellant-opponent 3 to react thereto, e.g. by providing further experiments. As a result, appellant-opponent 3 requested that, if auxiliary

requests 3 and 15 were admitted into the proceedings, the proceedings be continued in writing.

6.6 The Board is of the view that the amendment limiting the dosage forms to capsules is not complex and directly addresses the issue on file. Moreover, contrary to the opinion of appellant-opponent 3, the appellant is not in a worse position because of filing D44, since inventiveness of the main request was denied as a consequence of the results of D44. Furthermore, the respondent must be entitled to defend their case in response to new data provided by the appellants-opponents within the framework of the Rules of Procedures of the Boards of Appeal. Depriving the respondent therefrom as a matter of principle would represent a procedural violation. Accordingly, the submission of auxiliary requests 3 and 15 with the reply to the appeals, *i.e.* as early as possible in reaction to the submission of D44 with the statement of grounds of appeal, is not against procedural economy.

6.7 As a consequence, auxiliary requests 3 and 15 are admitted into the appeal proceedings (Article 12(4) RPBA).

6.8 Furthermore, the request of appellant-opponent 3 that the proceedings be continued in writing is rejected.

Allowing this request would be against the principle of procedural economy and the Board is unable to recognise any obvious reasons justifying this request. In particular, auxiliary requests 3 and 15 were filed on 6 March 2024 and the communication pursuant to Article 15(1) RPBA indicating the intention of the Board to admit these auxiliary requests was issued on 21 May 2025, *i.e.* almost two years, and 8 months before

the oral proceedings, respectively. The appellant-opponent 3 had therefore sufficient time to prepare an appropriate response to and attacks against these auxiliary requests.

*Auxiliary request 3*

7. Inventive step

7.1 The considerations regarding the choice of the closest prior art embodiment and the distinguishing feature made for the main request apply *mutatis mutandis* to present auxiliary request 3.

7.2 Claim 1 of auxiliary request 3 corresponds to claim 1 of the main request with the additional limitation that the composition is in the form of a capsule. Hence, the technical effect of the faster dissolution at early time points is considered to credibly occur over the whole scope of this amended claim, for the reasons detailed for the main request (see 4.3.5 to 4.3.16). Furthermore, for the reasons detailed under 4.3.13, this effect is useful and can be taken into account in the formulation of the objective technical problem.

In this context, appellant-opponent 3 argued during the oral proceedings that D13 would substantiate that the nature of the capsule material influences the dissolution. Hence, the technical effect would not credibly occur for any type of capsules. However, the Board observes that this finding of D13 concerned multilayered compositions of the prior art. There is no evidence that this would also be the case for the present compositions. This argument remains an unsubstantiated allegation.

7.3 As a result, starting from the multilayered compositions C1 or C2 of D1, the objective technical problem to be solved by the subject-matter of claim 1 of auxiliary request 3 resides in the provision of a DEM formulation with faster dissolution at early time points.

7.4 The Board considers that the skilled person would not have expected such a faster dissolution with a two-particle composition.

None of the cited prior art documents suggests that a faster dissolution at early time points would be achieved with a two-particle composition. Only D1 very generally mentions a two-particle composition but without any particular technical effect associated thereto.

7.5 The appellants-opponents argued that it would have been obvious for the skilled person to prepare a two-particle composition based on the sentence on page 14 lines 7 to 8 of D1. Appellant-opponent 3 further explained that the skilled person would have known from its common general knowledge (as apparent from D19, D36, D37 (see page 459, left column, second paragraph starting with line 9) and D38 (see page 349, left column, second paragraph)) that the disintegration of the capsule was the decisive factor for the dissolution of DEM. This was confirmed by the data of D44. Consequently, the skilled artisan was in a try and see situation as regards the "simple mixture" embodiment disclosed in D1. The appellants-opponents consider that the skilled person would have prepared this "simple mixture" in order to improve DEM dissolution and would have simply added a (super)disintegrant, such as CMC or

croscarmellose sodium, to increase the dissolution if required.

The Board does not share this view. As explained in detail for the main request, the Board considers that the data on file (see D45 and D44) substantiate that the technical effect can be attributed to the provision of a two-particle composition instead of a multilayered one. The skilled person would not have expected this teaching from the sentence on page 14 lines 7 to 8 of D1. The fact that dissolution may be influenced by further parameters (such as the addition of a disintegrant) cannot compensate for the lack of teaching of the present effect for the type of formulation prepared.

7.6 Appellant-opponent 2 considered that a faster initial dissolution would be expected for a two-particle composition compared to a multilayered composition. The outer layer, *i.e.* the one in contact with the exterior environment, of the final pellets of the multilayer compositions contained DEM, HPC and talc. Since talc and DEM were hydrophobic, a hydrophobic surface was exposed to the surroundings. Capsules containing these would have a low dissolution rate, as illustrated in the left part of Figure 17.4 of D19. In contrast, the two-particle composition contained acid particles corresponding to the isolated pellets of D1, which have an outer layer containing HPMC and talc. Since HPMC is hydrophilic, the outer layer would be less hydrophobic than the one of the multilayered one-particle composition.

In the Board's view, these considerations regarding the dissolution of both compositions due to the alleged hydrophobicity of the respective outer surfaces remains

speculative. There is no evidence that this conclusion would indeed have been obvious for the skilled person such that the present technical effect would indeed have been necessarily expected for the two-particle composition according to the claims compared to the multilayered one-particle composition of D1.

7.7 Accordingly, auxiliary request 3 fulfills the requirements of Article 56 EPC.

8. Amendments to the description

8.1 In example 3, paragraph [0088] of the patent, the original reference to US 2006/074056 was replaced by a reference to WO 2003/074056.

8.2 The respondent, in line with the impugned decision, considered this amendment as the correction of an obvious error and hence allowable. They argued that the correction would have been immediately apparent when doing a patent literature search with the name of the active ingredient and the part of the publication number, namely "074056" and any country code and publication year (see PatBase search results D29). The respondent further argued that also the PatBase search results provided by appellant-opponent 2 (see D31) indicated that only the first patent family including the patent WO 03/074056 made sense in the present context.

8.3 The Board considers that the correction of the number of the reference document cited in example 3 of the patent was not obvious.

The Board concurs with appellant-opponent 2 on the following points:

- (a) No literature search should be required to find the correction since an obvious correction in the sense of Rule 139 EPC can only be based on the original application and common general knowledge, and
- (b) the PatBase search performed by the respondent (results as D29) using the search term "PN = \*074056" was based on hindsight knowledge of the correct publication number. A further search with the search term "PN = US2006\*" retrieved 14 hits (see D31). It was therefore not immediately apparent that nothing else than the suggested correction was meant.

Independently of the issue of whether the family 1 of D31 would be the only one relevant in the context of the present patent, it is still the case that said patent family in D29 or D31 includes a very large number of individual patents, including W003/074056 but also for example US2003/181488. There is therefore more than one possible correction.

In this context the argument of the respondent provided during the oral proceedings that all the documents of one family would disclose the same subject-matter so that the actual choice made was not critical, is not conclusive. Firstly this is not a criteria under Rule 139 EPC and secondly there is no evidence that all the documents of this specific family do indeed have the exact same content.

8.4 As a result, the second condition for allowing a correction under Rule 139 EPC is not met and the amendment thus infringes the requirements of Article 123(2) EPC.

*Auxiliary request 15*

9. Auxiliary request 15 consists of:
  - the claims of auxiliary request 3 (claims 1 to 6),
  - an amended paragraph [0088] of the description filed with the reply to the appeals, and
  - the remaining paragraphs of the description of the main request as maintained in the opposition proceedings.
  
10. Paragraph [0088] was amended so as to reverse the reference to the prior art document to US2006/074056 as in the corresponding passage of the original description (see page 21 line 18 of the original description). This amendment directly addresses the finding of an unallowable correction of an obvious error for auxiliary request 3. Despite the numbering as auxiliary request 15, this request was hence considered next in accordance with the respondent.
  
11. Amendments
  - 11.1 The appellants-opponents did not raise any objection regarding the compliance of the claims of auxiliary request 3, which form the basis of auxiliary request 15, with Articles 123(2) and 123(3) EPC.
  
  - 11.2 Furthermore, as stated above (see point 9.), the amendment to paragraph [0088] overcomes the issue of lack of compliance with Article 123(2) EPC of auxiliary request 3.
  
  - 11.3 Hence, auxiliary request 15 fulfils the requirements of Articles 123(2) and (3) EPC.

12. Sufficiency of disclosure

The Board observes that the appellants-opponents did not pursue in the appeal stage the objection of lack of sufficiency of disclosure raised by opponent 1 during the opposition proceedings. The Board considers that auxiliary request 15 fulfils the requirements of Article 83 EPC.

13. Novelty and inventive step

Auxiliary request 15 complies with Articles 54 and 56 EPC for the same reasons as provided for the main request (novelty) and auxiliary request 3 (inventive step), respectively.

## Order

### For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of claims 1 to 6 of auxiliary request 3 filed with the reply to the appeals, paragraph [0088] of the description filed with the reply to the appeals, and the further paragraphs of the description to be adapted.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Usuelli

Decision electronically authenticated