

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

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

Case Number: T 0433/24 - 3.3.07

Application Number: 14717038.5

Publication Number: 2968172

IPC: A61K31/592, A61K31/593,
A61K47/38, A61K47/44, A61K9/20,
A61K9/28, A61K9/48, A61P1/00,
A61P3/00, A61P5/00, A61P7/00,
A61P9/00, A61P11/00, A61P13/00,
A61P15/00, A61P17/00,
A61P19/00, A61P21/00,
A61P25/00, A61P27/00

Language of the proceedings: EN

Title of invention:

STABILIZED MODIFIED RELEASE VITAMIN D FORMULATION AND METHOD
OF ADMINISTERING SAME

Patent Proprietor:

EirGen Pharma Ltd.

Opponent:

DSM Nutritional Products AG

Headword:

Stabilized vitamin D formulation / EIRGEN

Relevant legal provisions:

EPC Art. 100(c), 123(2), 54(2), 56, 117(1)(d)
RPBA 2020 Art. 12(1)(c), 12(4), 12(2)

Keyword:

Late-filed objection - admitted in first-instance proceedings
(yes) - admitted (yes)
Taking of evidence - hearing witness
Amendments - added subject-matter (main request: yes)
Novelty - auxiliary request (yes)
Inventive step - auxiliary request (yes)

Decisions cited:

T 0989/24, T 0332/87, G 0002/21



Beschwerdekammern
Boards of Appeal
Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0433/24 - 3.3.07

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

Appellant: EirGen Pharma Ltd.
(Patent Proprietor) Westside Business Park
Old Kilmeaden Road
Waterford X91 YV67 (IE)

Representative: Meissner Bolte Partnerschaft mbB
Patentanwälte Rechtsanwälte
Postfach 10 26 05
86016 Augsburg (DE)

Appellant: DSM Nutritional Products AG
(Opponent) Wurmisweg 576
4303 Kaiseraugst (CH)

Representative: Kraus & Lederer PartGmbH
Thomas-Wimmer-Ring 15
80539 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
22 January 2024 concerning maintenance of the
European Patent No. 2968172 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: E. Duval
L. Basterreix

Summary of Facts and Submissions

- I. The appeals were filed by the appellant-proprietor and the appellant-opponent against the interlocutory decision of the opposition division finding that, on the basis of auxiliary request 3, the patent met the requirements of the EPC.

The decision was based on the patent as granted (main request), and on auxiliary requests 1, 2 and 3, filed respectively as auxiliary requests 1, 2 and 4 with letter of 27 July 2023.

- II. Independent claims 1 and 2 of the main request read as follows:

"1. A controlled release oral formulation of a vitamin D compound comprising one or both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃, the formulation comprising a matrix that releasably binds and controllably releases the vitamin D compound, the matrix comprising a cellulose ether, wherein the cellulose ether is present in an amount of at least 5 of the formulation, based on the total weight of the formulation excluding any additional coatings or shells (wt%)."

"2. A stabilized oral formulation for controlled release of a vitamin D compound, said formulation comprising a mixture of:

one or both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃;
a wax matrix; and

a stabilizing agent, which comprises a cellulose ether, wherein the cellulose ether is present in an amount of at least 5% of the formulation, based on the total weight of the formulation excluding any additional coatings or shells (wt%)."

The main request additionally comprised the following dependent claim 16:

"16. The formulation or dosage form for use in a method of treatment of any of claims 12-15, wherein the patient:

- (a) has chronic kidney disease (CKD); or
- (b) has chronic kidney disease which is Stage 3 or 4; or
- (c) has chronic kidney disease which is Stage 3 or 4 and is vitamin-D deficient."

In auxiliary request 1, claim 16 additionally specified that "the disease is secondary hyperparathyroidism", and claims 19 and 20 were deleted.

In auxiliary request 3, claim 1 was limited to a wax matrix.

III. The following documents were cited in the appealed decision:

- D3: WO 2008/134512
- D5: A. Nokhodchi et al., Bioimpacts 2012, 2(4):175-187
- D7: WO 92/09271
- D8: EP-A 116 755
- D9: WO 91/16899
- D22: WO 99/01111
- D24: EP-A 413 828
- D26: WO 2003/059358 A1

D27: WO 2009/101131 A1
D28: WO 2009/101136 A1
D60b: Declaration of Colm Nulty
D63: affidavit of Charles W. Bishop
D63c: European Pharmacopoeia monograph for calcifediol ("Exhibit C")
D66: Rowe et al., "Handbook of Pharmaceutical Excipients", 6th edition, 2009, pp. 317-321 and 326-329.
D70: second affidavit by Charles W. Bishop
D79: M. Levina "Influence of Fillers, Compression Force, Film Coatings & Storage Conditions on performance of Hypromellose Matrices", Drug Delivery Technology 2004, 4(1):34-42

IV. The opposition division decided that:

(a) The chronic kidney disease recited in claim 16 of the main request without reference to secondary hyperparathyroidism, as well as claims 19 and 20, infringed Article 123(2) EPC.

(b) Auxiliary request 1 was admitted into the proceedings, and met the requirements of Article 123(2) EPC and of sufficiency of disclosure.

Regarding novelty, D26, disclosing a matrix comprising a cellulosic ether, 25-hydroxyvitamin D₃, and oil, anticipated the subject-matter of claim 1.

(c) Auxiliary request 3 was admitted into the proceedings. This request met the requirements of Article 123(2) EPC. The feature "wax matrix" established novelty over D26.

D79 was admitted into the proceedings.

As to inventive step, starting from D3, the distinguishing feature was the presence of cellulose ether in an amount of at least 5 wt% of the formulation, based on the total weight of the formulation excluding any additional coatings or shells. The technical problem was the provision of a formulation with improved stability of the release profile. The claimed solution involved an inventive step.

- V. The Board set out their preliminary opinion in a communication under Article 15(1) RPBA.
- VI. Oral proceedings were held before the Board.
- VII. The requests of the parties were the following:
 - (a) The appellant-proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted, or, subsidiarily, that the patent be maintained on the basis of one of auxiliary requests 1-15, corresponding respectively to auxiliary requests 1, 2 and 4-16 filed on 27 July 2023.

The appellant-proprietor further requested that:
- the ground of opposition under Article 100(c) EPC, and
- document D79
be not admitted into the proceedings.

Lastly, the appellant-proprietor requested that Charles W.Bishop and Colm Nulty be summoned as witnesses.

- (b) The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

VIII. The appellant-proprietor's arguments may be summarised as follows:

- (a) The ground of opposition under Article 100(c) EPC was not to be admitted in the proceedings, because it had not been duly substantiated in the notice of opposition. Likewise D79 was not to be admitted, because it was not *prima facie* relevant and had not been submitted in due time.
- (b) Claim 16 did not introduce added subject-matter, because paragraph [0076] of the description as filed recited the treatment of patients having CKD without mentioning secondary hyperparathyroidism.
- (c) The claimed subject-matter was novel over D26. There were reasons that prevented a skilled person from making a combination of examples 3-4, showing compositions comprising the modified starch CAPSUL®, and of the passages on page 6 regarding the alternative use of cellulose ethers.
- (d) Regarding inventive step, D3 was the closest prior art. The technical effect accomplished by the invention was not the stabilization of 25-hydroxyvitamin D₂/D₃ against degradation. Instead, the objective technical problem was to provide a controlled release 25-hydroxyvitamin D₂/D₃ formulation that retained the dissolution release profile during storage. The solution involved an inventive step in view of D9, D22, D79, D66 and D5.

D26 was not the closest prior art. If taken as starting point, examples 3 and 4 of D26 could not be reproduced by replacing the modified starch CAPSUL® with a cellulose ether, for reasons of incompatible viscosity.

IX. The appellant-opponent's arguments may be summarised as follows:

- (a) The appellant-proprietor's request not to admit the ground for opposition under Article 100(c) EPC was not justified. A request, allegation of fact, or ground for opposition already admitted in first instance and discussed in detail in the appealed decision was part of the appeal proceedings and should not be excluded.
- (b) In claim 16 of the main request relating to the treatment of CKD, omitting "secondary hyperparathyroidism" (present in original claims 68-71) introduced added subject-matter. Paragraph [0076] only described patients at risk of vitamin D deficiency and was not a suitable basis either.
- (c) Only one selection from the list of encapsulating agents in D26 was needed to arrive at the subject-matter of claim 1, namely the choice of HPMC to replace CAPSUL® in the examples. Likewise, the claimed subject-matter lacked novelty as it required only one selection in D7, D8, D9, D24, D27 and D28.
- (d) As to inventive step, D3 and D26 were both suitable closest prior art. Starting from D3, the difference was the presence of ≥ 5 wt% cellulose ether. The

objective technical problem was the provision of a formulation with improved storage stability. The claimed solution was obvious in light of D66, D5, D22 or D79.

Reasons for the Decision

1. Admittance of the ground under Article 100(c) EPC and of D79
 - 1.1 The ground for opposition under Article 100(c) EPC was admitted by the opposition division (see §2.1 on pages 7.8 of the appealed decision), was assessed as to its substance (see §2.2-§2.5), and is part of the appellant-proprietor's case in appeal (see §1 of their reply). According to Article 12(1) and (2) RPBA, this ground is part of the appeal proceedings, and its admittance is not subject to the Board's discretionary power under any of Article 12(4) and (6) RPBA. As explained in the Case Law of the Boards of Appeal (11th edition, 2025, V.A.3.4.3), there is no legal basis for "un-admitting" this part of the parties' cases in appeal under these circumstances.
 - 1.2 Document D79, which was likewise admitted by the opposition division, considered as to its content, and relied on by the appellant-opponent in appeal, is also part of the appeal proceedings for the same reasons.
2. Request for witnesses to be summoned

The appellant-proprietor requested in writing that Mr Bishop and Mr Nulty be summoned as witnesses.

Mr Bishop was already allowed to make submissions on technical issues as a person accompanying the representative during the oral proceedings before the opposition division (see the Minutes, §20; the appealed decision, §6.1.1, page 21). Mr Bishop and Mr Nulty are also the authors of the written declarations / affidavit D60b, D63 and D70.

The Board did not consider that the conditions for summoning Mr Bishop or Mr Nulty as witnesses in the sense of Article 117(1)(d) EPC were met. Firstly, a party who wishes to adduce witness evidence should indicate what factual details it wishes to prove by this means. The appellant-proprietor provided no such indication in the appeal proceedings. Secondly, a witness is put forward to substantiate facts of which they have personal knowledge (Case Law of the Boards of Appeal, 11th edition, 2025 II.G.2.4.2). Here, the submissions by Mr Bishop and Mr Nulty in the first instance proceedings pertained not to events in the past but to issues of claim interpretation and novelty.

Accordingly, the request to summon Mr Bishop and Mr Nulty as witnesses was refused.

3. Main request (patent as granted), Article 100(c) EPC
- 3.1 Claim 16 relates to the "formulation or dosage form for use in a method of treatment of any of claims 12-15, wherein the patient: (a) has chronic kidney disease (CKD); or (b) has chronic kidney disease which is Stage 3 or 4; or (c) has chronic kidney disease which is Stage 3 or 4 and is vitamin-D deficient".

The appellant-proprietor cited claims 68-71 and paragraph [0076] of the application as filed as basis for claim 16.

3.1.1 The Board concurs with the opposition division that claims 68-71 as filed only disclose that the patient has CKD in the context of secondary hyperparathyroidism, and do not provide a basis for the omission of secondary hyperparathyroidism as in claim 16.

3.1.2 Paragraph [0076] discloses that "Patients in need of vitamin D supplementation include healthy subjects and subjects at risk for vitamin D insufficiency or deficiency, for example, subjects with Stage 1, 2, 3, 4 or 5 CKD". The Board concurs with the appellant-opponent that paragraph [0076] only refers to patients in need of vitamin D supplementation, which limitation is lacking from claim 16. No basis was given for the omission of this limitation.

3.1.3 Hence, claim 16 infringes Article 123(2) EPC.

3.2 Since the main request must be rejected for this reason already, it is not necessary to determine whether claims 19 and 20 of the main request also add subject-matter.

4. Auxiliary request 1

4.1 Article 123(2) EPC

In auxiliary request 1, claim 16 additionally specified that "the disease is secondary hyperparathyroidism", and claims 19 and 20 were deleted. The above issue of added subject-matter is thus overcome. The appellant-

opponent had no objection of added subject-matter against auxiliary request 1.

Auxiliary request 1 complies with the requirement of Article 123(2) EPC.

4.2 Novelty

4.2.1 The appellant-opponent raised objections of lack of novelty over D26, as well as D7-D9, D24, D27 and D28. However, the appellant-opponent does not argue that, in any of these documents, the general disclosure alone, or the examples alone, anticipate the claimed subject-matter.

Instead, in each case, the appellant-opponent considers the claimed subject-matter to lack novelty over an embodiment resulting from the exchange, in one or more example(s), of one component for an alternative component mentioned in the general part of the same document, and argues that this embodiment results from a single selection. The embodiments are:

- the combination, in D26, of:
 - examples 3 and 4 (see pages 14-15), showing a microencapsulated oil formulation comprising 25-hydroxyvitamin D₃ and at least 5 wt % of a modified starch (CAPSUL®) as encapsulating agent, with
 - the general passages on page 6, lines 4-7 and 21-23, reciting fourteen preferred encapsulating agents among which, beside starches, cellulose derivatives such as cellulose ethers;

- the combination in D7 of:
 - example 1 (see pages 7 and 8) showing a composition comprising a different vitamin D

compound (ST-630) and more than 5 wt% cellulose ether (HPMC), with

- the general passage on page 4, line 11, listing numerous vitamin D compounds for use in the invention, among which "ST-630" and 25-hydroxyvitamin D₃ (25-hydroxycholecalciferol);

- the combination in D8 of:

- example 25 (page 19), showing a composition of 1 α -hydroxyvitamin D₃ containing more than 5 wt% HPMC, with

- the list on page 4, line 34, listing 25-hydroxyvitamin D₃ and 1 α -hydroxyvitamin D₃ in a list of vitamin D₃ compounds;

- the combination in D9 of:

- example 5 on page 11, showing a composition comprising ST-630, hydroxypropylcellulose, PVP and mannitol, with

- the general list of vitamin D derivatives on page 4, line 21, citing 25-hydroxyvitamin D₃ beside ST-630;

- the combination in D24 of:

- examples 4-6 in table 2 on page 7, comprising different vitamin D₃ forms and HPC or HPMC, with

- the mention of 25-hydroxyvitamin D₃ (see page 4, lines 7-16) among the vitamin D₃ derivatives;

- the combination in D27 of:

- example 1 (spray-dried formulation of 25-hydroxyvitamin D₃ comprising 73.2% modified food starch) with

- the general description of D27 (page 6, lines 18-21, and page 7, lines 5-7) mentioning cellulose

derivatives such as hydroxypropylcellulose or HPMC as alternative to starch;
or the equivalent passages of D28 (example 1 on page 13, lines 2-6, with page 6, lines 16-23, and page 7, lines 7-9).

- 4.2.2 While the disclosure of a document normally has to be considered as a whole, it is not permissible to combine separate items belonging to different embodiments described in one and the same document, unless such combination is specifically suggested (see also the Case Law of the Boards of Appeal, 11th edition, 2025, I.C.4.1 and I.C.4.2).

In the above objections, the examples each teach either the use of a vitamin D compound other than 25-hydroxyvitamin D₂ or D₃, or the use of excipients/encapsulating agent other than a cellulose ether. These examples cannot be regarded as lists from which the components may be selected, but instead represent complete descriptions of the formulations which do not need to be completed or combined with the general disclosure as regards these components. In each case, the document does not point to the replacement of one component in these particular examples with another component generally mentioned, while keeping all other features of the example unchanged, and in particular the amounts. None of the documents disclose the combination of 25-hydroxyvitamin D₂ or D₃ together with a cellulose ether in the claimed amounts (at least 5 wt%).

- 4.2.3 The opposition division based their finding of lack of novelty over D26 on decision T 332/87, which states that "when examining novelty, different passages of one document may be combined provided that there are no

reasons which would prevent a skilled person from such a combination. In general the technical teaching of examples may be combined with that disclosed elsewhere in the same document, e.g. in the description of a patent document, provided that the example concerned is indeed representative for the general technical teaching disclosed in the respective document" (see point 2.2 of the reasons, cited in §6.2 of the appealed decision).

The Board however emphasises that, for the purposes of novelty, the content of the prior art is assessed using the same disclosure test as for e.g. added subject-matter (see the importance of applying a uniform concept of disclosure for the purposes of Articles 54, 87 and 123 EPC recalled in G 2/10, point 4.6 of the reasons, and G 1/03, point 2.2.2 of the reasons). For concluding to a lack of novelty there must be a direct and unambiguous disclosure in the state of the art of the claimed subject-matter. T 332/87 does not contradict the established principle that a direct and unambiguous disclosure of the claimed features in combination is needed for novelty to be denied. This combination of feature does not derive from an item of the prior art merely because of the absence of reasons for not considering the combination. Indeed, in T 332/87, claim 1 of the main request pertained to an aqueous composition containing filler material and a particular emulsion polymer. Example 7 of the prior art document disclosed such an emulsion polymer, whereas page 13 of that document indicated that these emulsions could be modified by incorporation of fillers. The example was hence not modified, but merely completed on the basis of the general disclosure of the same document. In contrast, the present situation is rather akin to that underlying T 568/11 (point 2.1 of the

reasons): the skilled person reading the example would not seek any missing information regarding the components of the composition because this information is already specified with these examples.

4.2.4 Accordingly, auxiliary request 1 meets the criteria of novelty.

4.3 Inventive step

4.3.1 Both parties consider D3 as a suitable starting point for the assessment of inventive step. The Board concurs.

D3 relates to a controlled release oral formulation of a vitamin D compound, in particular 25-hydroxyvitamin D₃, the formulation comprising a waxy controlled release carrier agent that releasably binds and controllably releases the vitamin D compound (see claim 1).

4.3.2 The subject-matter of claim 1 differs from D3 in that the formulation comprises at least 5 wt% of a cellulose ether, based on the total weight of the formulation excluding any additional coatings or shells.

4.3.3 The appellant-opponent does not contest that the technical effect resulting from this difference is a higher stability of the dissolution release profile upon storage (see §13.3 of the impugned decision; §6.2.2 of the appellant-opponent's grounds of appeal, and §3.4.2 of their reply).

The appellant-opponent however argues that the problem to be solved should be formulated in a more general way. Citing paragraphs [0001], [0006] and [0014] of the

patent, the appellant-opponent submitted that the problem should not be worded specifically as referring to an improved stability of the dissolution release profile upon storage, but more generally as improving storage stability. The appellant-opponent expressed in particular the view that a stable dissolution release profile required the active ingredient to be stable.

The appellant-proprietor countered that the technical effect accomplished by the invention was not stabilization of 25-hydroxyvitamin D₂/D₃ against degradation.

This question is important because formulating the technical problem in a more general way may lead to the specific contribution of the invention to the art being disregarded. Stability is a general term which may refer to different properties beside storage stability, such as stability under specific conditions or consistent stability across production batches, and can relate to the stability of the active ingredient or stability of other characteristics of the whole composition. The question is accordingly whether a specific technical effect is shown and whether this specificity should be reflected in the objective technical problem.

In the Board's view, paragraphs [0001] and [0014] of the patent mention a technical problem in general terms, namely the provision of controlled-release formulations "which are shelf-stable over time", or having "improved "storage stability", or stability following ageing, as well as one or more additional characteristics including improved physical, chemical and biological properties". However, paragraph [0006] is more specific, i.e. it mentions the problem of

providing "compositions that retain the desired dissolution properties of the formulation, for extended periods of time, e.g., after shipping and storage". Likewise, paragraph [0024] defines stability as referring to "stable *in vitro* dissolution profile [...] following actual shelf storage".

In the Board's view, the fact that the problem to be solved is additionally worded in general terms in the patent does not on its own preclude that the problem as part of the problem-solution approach be formulated in a more specific way, depending on the evidence offered and subject to the requirements of G 2/21.

Even if the description as filed mentioned generally the problem of chemical and physical stability, including stability of the vitamin D active ingredient, the application as filed already contained evidence showing the specific effect on the dissolution release profile upon storage (see figures 3A and 3B), as well as evidence that the vitamin D content did not, or barely, decrease when stored for months (see [0091] of the patent or [0096] of the application as filed: for a dissolution time of 12 hours, the coefficient of variation %CV goes from 118.7 at 1 month to 112.6 at 6 months). The fact that the observed increased stability of the *in vitro* dissolution profile is not mediated by an improved stability of the 25-hydroxyvitamin D₃/D₂ active agent is confirmed by D63b, as explained in the appealed decision (see pages 42-43 of the grounds for the decision).

Thus, it has been shown that the differentiating feature, namely the presence of at least 5 wt% of a cellulose ether, leads to an improved stability of the dissolution release profile during storage, and that

this effect is not mediated by a stabilization of 25-hydroxyvitamin D₂/D₃ against degradation. This specific technical effect is shown in the application as filed for exemplified compositions according to claims 1 and 2, i.e. it is encompassed by the technical teaching of the application as filed and embodied by the same originally disclosed invention. Consequently, it may be relied upon in the assessment of inventive step, following G 2/21.

- 4.3.4 Accordingly, the objective technical problem may be formulated as the provision of a formulation with improved stability of the dissolution release profile upon storage.

The appellant-opponent briefly questioned, during the oral proceedings before the Board, whether the above problem was solved over the whole scope of claim 1. However, the appellant-opponent neither substantiated their allegation that the above technical effect could not be extrapolated to the whole claimed area, nor drew any conclusion from their allegation as regards inventive step.

- 4.3.5 The appellant-opponent relies on common general knowledge, as reflected in D66 or D5, or the teaching of D9, D22 or D79, to argue that the claimed solution is obvious.

The handbook D66 contains a general teaching that HPMC is useful, among others, as stabilising agent in cosmetics and in food products (see page 318, left-hand column; see also page 326 for hypromellose). This teaching is entirely unspecific as to the type of stability referred to, and it provides no hint that cellulose ethers could improve the stability of the

dissolution release profile upon storage in the claimed 25-hydroxyvitamin D₂ or D₃ formulations.

The review article D5 states that HPMC "is used as first choice for the formulation of hydrophilic matrix systems as it provides a robust mechanism for controlled release of drugs and choice of viscosity grades. Its non ionic nature minimises interaction problems when used in acidic, basic or electrolytic systems and provides reproducible release profiles". HPMC is also "a material of great importance when used as a carrier in drug release systems" (see page 178, right-hand column; page 180, left-hand column). However, the term "reproducible release profiles" expresses that the release profile is reproducible, e.g. across production batches, but does not clearly relate to stability of the dissolution profile over time.

D9 pertains to the stabilization of solid pharmaceutical preparations of vitamin D₃ derivatives (see page 2, line 24 to page 3, line 4), including 25-hydroxyvitamin D₃ (see page 4, line 20). D9 suggests adding hydroxypropyl cellulose as a degradative agent in an amount of 5-30% by weight to increase stability of the derivative (see page 3, lines 12-13; page 5, lines 10-13). As explained above, the technical effect of the invention is not the stabilisation of the active ingredient, but the stabilisation of the dissolution release profile during storage. Hence the skilled person would not apply the teaching of D9 in the expectation of solving the above problem.

The research article D79 generally states that cellulose ethers such as HPMC "have been widely studied for their applications in oral SR systems since the

early 1960s. Formulation development is simple and reproducible release profiles are well documented" (see the introduction). This introduction does not relate to the same effect as obtained by the claimed invention, similarly to D5. D79 further mentions that "cellulose ethers are generally very stable [...] . Normal storage conditions will not generally affect drug release" (see D79, page 38, left column, last paragraph). However, this further statement is made in the context of the studies in D79 pertaining to the different active agents chlorpheniramine maleate or theophylline. Considering that D79 also states that the drug release from HPMC depends on the drug (see the introduction), the skilled person would not anticipate that the use of cellulose ethers would solve the above problem in the context of the claimed 25-hydroxyvitamin D₂/D₃ formulations.

The general introduction of D22 mentions the stability of a pharmaceutical dosage form with respect to several properties (page 1, lines 14-19). The document then addresses the problem of maintaining the dissolution profile of the formulation after storage only in the context of a different active ingredient, namely tramadol (see page 5, lines 8-17). The Board concurs with the appellant-proprietor that the teaching of D22 is limited to tramadol, because D22 emphasizes the specificity of the problem in the context of tablets containing large amounts (>40 wt%) of tramadol (see page 11, lines 17-20). The skilled person would not extrapolate this teaching to the claimed 25-hydroxyvitamin D₂/D₃ formulations. The Board also shares the appellant-proprietor's view that the solution proposed in D22 to obtain a stable dissolution profile is a step of curing the dosage form, and not the presence of the cellulose ether (see claim 1 of

D22: "said solid dosage form being cured [...] such that [...] said solid dosage form provides a stable dissolution profile").

- 4.3.6 In a further line of argumentation, the appellant-opponent starts from D26.

For the reasons given above (see 4.2.2), the Board considers that D26 does not disclose the presence of at least 5 wt% cellulose ether in combination with 25-hydroxyvitamin D₂ or D₃. Starting from the starch-encapsulated formulations of 25-hydroxyvitamin D₃ of D26 (examples 3 and 4), the claimed subject-matter still differs at least by the presence of at least 5 wt% of a cellulose ether, based on the total weight of the formulation excluding any additional coatings or shells. Thus, D26 does not come closer to the claimed invention than D3.

- 4.3.7 Accordingly, the claimed invention involves an inventive step.

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 on the basis of the claims of auxiliary request 1 filed with the statement of grounds of appeal and corresponding to auxiliary request 1 filed on 27 July 2023, and a description to be adapted.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated