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**Datasheet for the decision
of 10 March 2026**

Case Number: T 0434/24 - 3.3.07

Application Number: 18155036.9

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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:

Vitamin D formulation / EIRGEN

Relevant legal provisions:

EPC Art. 76(1), 123(2)

Keyword:

Amendments - added subject-matter (yes)



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0434/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 March 2026

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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. 3332773 in amended form.**

Composition of the Board:

Chairman A. Usuelli
Members: E. Duval
Y. Podbielski

Summary of Facts and Submissions

- I. The patent proprietor and, initially, the opponent, appealed against the interlocutory decision of the opposition division finding that, on the basis of the auxiliary request 2, the patent met the requirements of the EPC.

The decision was based on a main request filed on 27 July 2023 and on auxiliary requests 1 and 2, both filed during the oral proceedings before the opposition division.

- II. Claim 1 of the main request read as follows

"A stabilized oral formulation for sustained release of a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation, the formulation comprising a mixture of:

one or both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃;

a stabilizing agent which is a cellulosic compound, wherein the stabilizing agent is present in an amount of at least about 5% of the formulation, based on the total weight of the formulation excluding any additional coatings or shells (wt%), which is effective to maintain a difference of less than 30% between the amount of vitamin D compound released at any given time point after four hours during *in vitro* dissolution after two months exposure to storage conditions of 25°C and 60% relative humidity and the amount released at the same dissolution time point during *in vitro*

dissolution conducted prior to exposing the formulation to the storage conditions; and
a secondary additive comprising one or more compounds selected from the group consisting of: calcium salts, bisphosphonates, calcimimetics, nicotinic acid, iron, phosphate binders, cholecalciferol, ergocalciferol, active Vitamin D sterols, glycemic control agents, hypertension control agents, antineoplastic agents, and inhibitors of CYP24, inhibitors of cytochrome P450 enzymes that can degrade vitamin D agents."

III. In auxiliary request 1, claim 1 specified the additional presence of "a wax matrix", and the list for the secondary additive was limited to "one or more compounds selected from the group consisting of: cholecalciferol and ergocalciferol".

IV. The opposition division decided that:

(a) Claim 1 of the main request resulted from the undisclosed combination of features in the earlier application as filed.

(b) Auxiliary request 1 was admitted into the proceedings. However, the feature of claim 1 relating to the secondary additive comprising cholecalciferol and/or ergocalciferol represented added subject-matter.

(c) Auxiliary request 2 was admitted into the proceedings and was found allowable.

V. With their statement setting out the grounds of appeal, the patent proprietor (appellant) defended their case on the basis of the main request filed on 27 July 2023 (see II. above), of auxiliary request 1 corresponding

to auxiliary request 5 filed on 27 July 2023, and of auxiliary request 2 corresponding to auxiliary request 1 filed during the oral proceedings on 28 November 2023 (see III.).

In auxiliary request 1 (former auxiliary request 5), claim 1 corresponded to claim 1 of the main request with the addition that the formulation comprised "a wax matrix".

- VI. With their reply to the opponent's appeal, the patent proprietor further refiled auxiliary request 3 corresponding to auxiliary request 2 filed during the oral proceedings on 28 November 2023 and allowed by opposition division, and auxiliary requests 4-15 corresponding respectively to auxiliary requests 2, 7, 8, 3, 4 and 9-15 filed on 27 July 2023.
- VII. The Board set out their preliminary opinion in a communication under Article 15(1) RPBA.
- VIII. Oral proceedings were held before the Board by videoconferencing.

At the end of the oral proceedings, the opponent withdrew their appeal and is thus respondent in the appeal proceedings.

The patent proprietor is the sole appellant and requests that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 27 July 2023, or that the patent be maintained on the basis of one of the following auxiliary requests:

- auxiliary request 1, corresponding to auxiliary request 5 filed on 27 July 2023;

- auxiliary request 2, corresponding to auxiliary request 1 filed during the oral proceedings on 28 November 2023;
- auxiliary request 3, corresponding to auxiliary request 2 filed during the oral proceedings on 28 November 2023 and allowed by opposition division;
- auxiliary requests 4-15, corresponding respectively to auxiliary requests 2, 7, 8, 3, 4 and 9-15 filed on 27 July 2023.

IX. The appellant's arguments regarding added subject-matter may be summarised as follows:

- (a) The secondary additives recited in claim 1 of the main request and of auxiliary request 1 were disclosed in paragraph [0088] of the earlier application as filed. Paragraph [0070] of the earlier application stated that "advantageously, 25-hydroxyvitamin D₂, 25-hydroxyvitamin D₃ or combinations thereof together with other therapeutic agents can be administered, e.g. orally, in accordance with the above described embodiments". Paragraph [0088] then disclosed the additives.

Accordingly, neither the main request nor auxiliary request 1 introduced any added subject-matter.

- (b) Regarding auxiliary request 2, claim 2 of the earlier application as filed stated that the formulation comprised one or both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃, without excluding the presence of further vitamin D compounds. Paragraph [0028] of the earlier application as filed stated that combinations of vitamin D compounds were contemplated for inclusion

in the formulation. The selection of 25-hydroxyvitamin D₂, 25-hydroxyvitamin D₃, cholecalciferol and ergocalciferol from this paragraph was only one selection. Furthermore, paragraph [0070] of the earlier application as filed contained a pointer that combinations could be advantageous.

Accordingly, auxiliary request 2 did not introduce added subject-matter.

X. The respondent's arguments may be summarised as follows:

(a) Regarding claim 1 of the main request and of auxiliary request 1, paragraph [0088] only generally described the administration of a vitamin D compound with other therapeutic agents. However, there was no direct and unambiguous disclosure that the secondary additive was comprised in the same formulation as the vitamin D compound. The administration of the vitamin D compound and other therapeutic agents could also be provided by administering two separate formulations.

Accordingly, the main request and auxiliary request 1 both introduced added subject-matter.

(b) As to auxiliary 2, paragraph [0028] provided a list of specific examples of vitamin D compounds, but did not directly and unambiguously disclose the specific combination of active agents as mandated by claim 1, namely a first additive selected from 25-hydroxyvitamin D₃ and/or 25-hydroxyvitamin D₂; and a secondary additive selected from cholecalciferol and/or ergocalciferol.

In addition, paragraph [0070] was not limited to the active ingredients all being in the same formulation, and it referred to dosage amounts of 1 to 100 µg per day, which was not a feature of claim 1.

Accordingly, auxiliary request 2 introduced added subject-matter.

Reasons for the Decision

1. Main request, Articles 76(1) and 123(2) EPC
- 1.1 The patent derives from a divisional application. The earlier application as filed was published under the PCT as WO 2014/143941 A1. The requirements of Article 76(1) EPC are examined below with respect to claim 1.
- 1.2 Claim 1 differs from paragraph [0144] of the earlier application as filed as follows (additions and ~~deletions~~ emphasised by the Board):

"A stabilized oral formulation for ~~controlled-sustained~~ release of a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation, the formulation comprising a mixture of:

one or both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃;

~~and an effective amount~~ a stabilizing agent which is ~~optionally~~ a cellulosic compound, wherein the stabilizing agent is present in an amount of at least about 5% of the formulation, based on the total weight of the formulation excluding any additional coatings or shells (wt%), which is effective to maintain a difference of less than 30%

between the amount of vitamin D compound released at any given time point after four hours during *in vitro* dissolution after two months exposure to storage conditions of 25°C and 60% relative humidity and the amount released at the same dissolution time point during *in vitro* dissolution conducted prior to exposing the formulation to the storage conditions; and
a secondary additive comprising one or more compounds selected from the group consisting of: calcium salts, bisphosphonates, calcimimetics, nicotinic acid, iron, phosphate binders, cholecalciferol, ergocalciferol, active Vitamin D sterols, glycemic control agents, hypertension control agents, antineoplastic agents, and inhibitors of CYP24, inhibitors of cytochrome P450 enzymes that can degrade vitamin D agents."

- 1.3 The appellant cites paragraphs [0070] and [0088] of the earlier application as filed as basis for the list of secondary additives.

Paragraph [0088] mentions the possible administration of the vitamin D compound in combination with one or more other therapeutic agent(s). The list of these further therapeutic agents corresponds to the secondary additives recited in claim 1. However, it is not stated in paragraph [0088] that these further therapeutic agents are included in the claimed stabilized oral formulation for sustained release of a vitamin D compound, as required by claim 1 of the main request, but merely that they are present "in the combination". The combined administration of these agents could also be provided by administering two separate formulations.

Paragraph [0070] of the earlier application as filed does not provide a suitable basis for this feature either, since it neither discloses the list of secondary additives of claim 1 nor goes beyond mentioning the administration of "25-hydroxyvitamin D₂, 25-hydroxyvitamin D₃ or combinations thereof together with other therapeutic agents". Thus paragraph [0070] does not disclose either that the other therapeutic agents are included in the same stabilized oral formulation for sustained release of a vitamin D compound.

1.4 Accordingly, claim 1 of the main request does not meet the criteria of Article 76(1) EPC.

1.5 The divisional as filed contains the same disclosure as the parent application as filed, with the parent claims appended in paragraph [0016]. Consequently, the main request does not meet the criteria of Article 123(2) EPC either.

2. Auxiliary request 1

In auxiliary request 1, claim 1 additionally specifies that the formulation comprises "a wax matrix". This amendment does not modify the above assessment regarding added subject-matter. Claim 1 of auxiliary request 1 still mandates that a secondary additive selected from the same list be comprised in the claimed stabilized oral formulation for sustained release of a vitamin D compound.

Consequently, auxiliary request 1 infringes Articles 76(1) and 123(2) EPC for the same reasons as for the main request.

3. Auxiliary request 2

3.1 in auxiliary request 2, the secondary additive is limited to "one or more compounds selected from the group consisting of: cholecalciferol and ergocalciferol".

Thus claim 1 specifies the presence of "one or both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃" in combination, in the same formulation, with "a secondary additive comprising one or more compounds selected from the group consisting of: cholecalciferol and ergocalciferol". The appellant-proprietor refers to claim 2 and paragraphs [0028] and [0070] of the earlier application as filed as basis for this combination.

The Board shares the opinion of the opposition division that this combination does not derive directly and unambiguously from the earlier application as filed. Paragraph [0028] first states that "Any vitamin D compound suitable for prophylactic and/or therapeutic use, and combinations thereof, are contemplated for inclusion in the formulation described herein". The paragraph then provides a list of twelve specific examples of vitamin D compounds, including cholecalciferol, ergocalciferol, 25-hydroxyvitamin D₃ and 25-hydroxyvitamin D₂. The claimed combination results from at least two selections from this list, or even more in the case of combinations with "both of 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃" or with cholecalciferol and ergocalciferol. Paragraph [0028] further discloses that "In one type of embodiment, the vitamin D compound includes one or more hydroxy forms, such as a combination of 25-hydroxyvitamin D₃ and 25-hydroxyvitamin D₂." This last embodiment neither discloses the presence of 25-hydroxyvitamin D₂ or 25-

hydroxyvitamin D₃, nor a combination with specifically cholecalciferol and/or ergocalciferol. Accordingly, the specific combinations defined in claim 1 of auxiliary request 2 are not individualised in the earlier application as filed, but are singled out by carrying out two or more independent selections from the same list.

Paragraph [0070] states that "25-hydroxyvitamin D₂, 25-hydroxyvitamin D₃ or combinations thereof together with other therapeutic agents can be administered, e.g. orally, in accordance with the above described embodiments in dosage amounts of from 1 to 100 µg per day, for example". This paragraph does not refer to cholecalciferol and/or ergocalciferol. In addition, this paragraph refers to a combined administration, but not clearly to the combined presence of these active agents in the claimed formulation. Lastly, this paragraph is limited to dosage amounts of 1 to 100 µg per day, which is not a feature of claim 1.

Claim 2 of the earlier application as filed does not refer to cholecalciferol and/or ergocalciferol either, nor to their presence in the same formulation.

Accordingly, auxiliary request 2 does not meet the requirements of Article 76(1) EPC.

4. Auxiliary request 3 corresponds to auxiliary request 2 allowed by the opposition division. Since the opponent withdrew their appeal, the maintenance of the patent according to auxiliary request 3 cannot be challenged (see G 4/93).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated