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Datasheet for the decision of 24 November 2025

Case Number: T 0180/24 - 3.3.07

Application Number: 19217651.9

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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:
Sustained release Vitamin D/EIRGEN

Relevant legal provisions:
EPC Art. 123(2), 123(3), 111(1)

Keyword:
Main request and auxiliary requests 1 and 2 - added subject-matter (yes)
Auxiliary request 3 - extension of protection (no) - remittal (yes)

Decisions cited:
G 0001/16

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Case Number: T 0180/24 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 24 November 2025

Appellant: (Patent Proprietor)	EirGen Pharma Ltd. Westside Business Park Old Kilmeaden Road Waterford X91 YV67 (IE)
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Respondent: (Opponent)	DSM Nutritional Products AG Wurmisweg 576 4303 Kaiseraugst (CH)
Representative:	Kraus & Lederer PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 8 December 2023 revoking European patent No. 3650016 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Molina de Alba
	A. Jimenez

Summary of Facts and Submissions

I. The decision under appeal is the opposition division's decision revoking the European patent. The decision is based on the patent as granted (main request) and the claims of 22 auxiliary requests.

II. Claims 1 as granted read as follows:

"*1. A stabilized formulation for sustained release of a vitamin D compound, the formulation comprising a mixture of:*
one or both of 25-hydroxyvitamin D_2 and
25-hydroxyvitamin D_3; and
a stabilizing agent comprising a material selected from the group consisting of: cellulose compounds, poloxamers, poly(ethylene oxide) polymers, povidones, fumed silicas, and combinations thereof, 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.*"

III. In the decision, the opposition division concluded that the patent as granted contained subject-matter which

extended beyond the content of the earliest application as filed (Article 100(c) EPC). Auxiliary requests 1 to 22 were admitted into the proceedings, but auxiliary requests 1 to 21 were also found to add subject-matter (Article 76(1) EPC) and auxiliary request 22 to extend the protection conferred by the patent as granted (Article 123(3) EPC).

IV. The patent proprietor (appellant) filed an appeal against the opposition division's decision. With its statement of grounds of appeal, the appellant filed the claims of a main request and 36 auxiliary requests.

The main request and auxiliary requests 1 to 12 were identical to auxiliary requests on which the decision was based, namely auxiliary requests 11, 12, 18, 22, 2, 3, 14, 15, 16, 17, 19, 20 and 21, respectively. Auxiliary requests 13 to 36 were new.

Claim 1 of the main request was identical to claim 1 as granted.

Claim 1 of auxiliary request 1 differed from claim 1 as granted in that the list of substances comprised in the stabilising agent was limited to a cellulosic compound, i.e. poloxamers, poly(ethylene oxide) polymers, povidones, fumed silicas and combinations thereof had been deleted from the list.

Claim 1 of auxiliary request 2 was directed to "*a sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a stabilised formulation*", wherein the stabilised formulation was as defined in claim 1 of auxiliary request 1.

Claim 1 of auxiliary request 3 read as follows:

"*1. A sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a stabilized formulation for controlled 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 D_2 and 25-hydroxyvitamin D_3;
and an effective amount of a stabilizing agent, which is a cellulosic compound, 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,*

wherein the formulation further comprises an oily vehicle,
wherein the oily vehicle comprises mineral oil, and wherein the formulation comprises about 20 wt% paraffin, about 20 wt% to about 25 wt% glycerol monostearate, about 10 wt% a mixture of lauroyl macrogolglycerides and lauroyl polyoxylglycerides, about 30 wt% to about 35 wt% mineral oil, and about 10 wt% to about 15 wt% hydroxyl propyl methylcellulose."

V. In its reply to the statement of grounds of appeal, the opponent (respondent) put forward arguments as to why the appeal should be dismissed.

VI. The board scheduled oral proceedings, in line with the parties' requests, and gave its preliminary opinion.

VII. Oral proceedings were held before the board. At the end of the oral proceedings, the board announced its decision.

VIII. The appellant's arguments, where relevant to the present decision, can be summarised as follows.

Main request

Claim 1 of the main request did not add subject-matter because it did not contain any new technical information which was not already included in the earliest application as filed. The claim had to be read in the context of the earliest application as a whole, which taught that the essence of the invention was to design a formulation with a storage-stable *in vitro* release profile that correlated with the *in vivo* release profile when administered to a subject. Although the earliest application generally referred to controlled release formulations, thorough reading, in particular of paragraphs [0026], [0006], [0007] and [0030] and the examples, made it clear that sustained release was the preferred form of controlled release and the focus of the invention. Nevertheless, the invention was not limited to sustained release in the gastrointestinal tract of a subject which ingested the formulation.

Taking this context into consideration, the main basis for claim 1 in the earliest application as filed could be found in the embodiments in paragraphs [0144] and [0036], combined with the stabilisers disclosed in paragraph [0050].

Although claim 1 did not contain the feature in paragraph [0144] that the formulation had to be suitable for sustained release "in the gastrointestinal tract of a subject which ingests the formulation", this feature was implicit in the claim; the functional part of claim 1 required a stable *in vitro* dissolution profile over time which rendered the claimed formulation suitable for sustained release into the gastrointestinal tract of a subject which ingested the formulation. The opponent's contention that the feature was not implicit because it was subsequently introduced in dependent claim 5 was flawed: the actual limitation of claim 5 over claim 1 was that the formulation was oral. In any case, the embodiment in paragraph [0144] could be generalised because paragraphs [0026] and [0036] did not contain the limitation that the sustained release had to occur in the gastrointestinal tract of a subject which ingested the formulation.

Starting from paragraph [0036], there was no limitation as to the place where the vitamin D compound had to be released in a sustained manner. Contrary to the opponent's view, paragraph [0036] was not limited by the disclosure in paragraph [0035]. Therefore, paragraph [0036], read in conjunction with paragraphs [0009], [0026], [0029], [0030] and [0050], provided a basis for a stabilised formulation as in claim 1 with no limitation as to the place where sustained release had to occur.

Auxiliary request 1

For the same reasons, claim 1 of auxiliary request 1 did not add subject-matter, either.

Auxiliary request 2

The primary basis for claim 1 of auxiliary request 2 in the earliest application as filed was paragraph [0144] in combination with paragraph [0168]. As the sustained-release forms recited in claim 1 of auxiliary request 2 were implicitly suitable for controlled release in the gastrointestinal tract of a subject which ingests the formulation, claim 1 of auxiliary request 2 did not add subject-matter, either.

Auxiliary request 3

Claim 1 of auxiliary request 3 did not extend the protection conferred by the patent as granted. The claim was based on claim 12 as granted, which was directed to a sustained-release dosage form comprising a formulation for sustained release of a vitamin D compound. Even if the formulation comprised in the dosage form of claim 1 was said to be for controlled release instead of sustained release, this did not broaden the limits of claim 12 as granted because the claimed product was still limited to a dosage form for sustained release. The skilled person would understand that the controlled-release formulation in the product in claim 1 was necessarily a sustained-release formulation; any other interpretation would not make technical sense. Furthermore, the formulation was inherently for sustained release, as could be derived from the *in vitro* dissolution requirements.

With regard to the amount of stabilising agent, the decision under appeal was flawed. Claim 1 contained 10 to 15% hydroxy propyl methylcellulose as the stabilising agent. Therefore, the stabilising agent was

present in an amount of at least 5% of the formulation, as required by claim 1 as granted.

Remittal

The opposition division only examined auxiliary request 22 (now auxiliary request 3) with regard to Article 123(2) and (3) EPC. Its preliminary opinion in preparation for the oral proceedings was not based on this claim request. As a consequence, if the board did not remit the case to the opposition division, it would have to carry out a full analysis of novelty, sufficiency of disclosure and inventive step for the first time, and would deprive the appellant of its right to have each ground for opposition raised by the respondent decided by two instances. Therefore, there were special reasons within the meaning of Article 11 RPBA to remit the case to the opposition division.

IX. The respondent's arguments, where relevant to the present decision, can be summarised as follows.

Main request

The embodiments in paragraphs [0144] and [0036] of the earliest application as filed did not support claim 1 of the main request. According to paragraph [0144], the stabilised formulation was for controlled release in the gastrointestinal tract of a subject which ingested the formulation. Paragraph [0036], read in the context of paragraph [0035], contained the same limitation and further required that the formulation contained a matrix component. In contrast, claim 1 of the main request defined a formulation for controlled release rather than sustained release, and failed to specify that the formulation was for release in the

gastrointestinal tract of a subject which ingested the formulation or that the formulation contained a matrix component. Contrary to the appellant's submissions, the limitation that the composition was for controlled release in the gastrointestinal tract of a subject which ingested the formulation was not implicit in claim 1. This was clear from the fact that the limitation was subsequently introduced in dependent claim 5. Therefore, claim 1 added subject-matter.

Auxiliary requests 1 and 2

The added subject-matter arguments put forward with regard to claim 1 of the main request were also applicable to claim 1 of auxiliary requests 1 and 2.

Auxiliary request 3

Claim 1 of auxiliary request 3 was based on claim 12 as granted. However, while claim 12 as granted was directed to a sustained-release dosage form comprising a formulation for sustained release, the formulation in claim 1 of auxiliary request 3 was for controlled release. Therefore, claim 1 of auxiliary request 3 could encompass embodiments not covered by the patent as granted, namely those in which the formulation comprised in the dosage form was for a type of controlled release that was not sustained. As a consequence, claim 1 of auxiliary request 3 extended the protection conferred by the patent as granted.

Remittal

Remitting the case to the opposition division would go against the principles of procedural economy and legal certainty. The grounds of sufficiency of disclosure,

novelty and inventive step had already been discussed in the opposition proceedings and the opposition division had given a negative preliminary opinion in relation to inventive step. Therefore, there were no special reasons for remittal.

X. The parties' final requests, where relevant to the present decision, were as follows.

- The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division on the basis of the claims of the main request filed with the statement of grounds of appeal.

  Alternatively, the appellant requested that the case be remitted to the opposition division on the basis of the claims of one of auxiliary requests 1 to 36, all filed with the statement of grounds of appeal.

  It also requested that auxiliary requests 13 to 36 be admitted into the appeal proceedings.

- The respondent requested that the appeal be dismissed, meaning that the patent be revoked in its entirety.

  In addition, the respondent requested that auxiliary requests 13 to 36 not be admitted into the appeal proceedings and that the case not be remitted to the opposition division.

Reasons for the Decision

1. Main request - added subject-matter (Article 76(1) EPC)

1.1 The patent is a second-generation divisional application. The parties and the opposition division agreed that the content of the earliest application as filed was identical to that of its PCT-publication, WO 2014/143941 A1, and discussed the issue of added subject-matter with reference to this PCT-publication (see also the decision, page 12, point 1). In the present decision, the board will also refer to WO 2014/143941 A1 as being equivalent to the earliest application as filed.

1.2 The appellant consistently argued that claim 1 of the main request does not add subject-matter because it does not contain any technical information that was not already disclosed in WO 2014/143941 A1. Not adding new technical information is a necessary condition for not adding subject-matter, but the standard of disclosure to be applied for the assessment of added subject-matter is the gold standard, as last confirmed by the Enlarged Board of Appeal in decision G 1/16 (OJ EPO 2018, A70, points 17 to 20 of the Reasons). This is the standard applied by the board in the present decision. It is defined as:

"*what a skilled person would derive directly and unambiguously, using common general knowledge and seen objectively and relative to the date of filing, from*

the whole of these documents [the application documents] as filed".

1.3 The primary basis for claim 1 of the main request in WO 2014/143941 A1 cited by the appellant is the combination of the embodiments in paragraphs [0144] or [0036] with the stabilisers disclosed in paragraph [0050].

1.4 Starting from paragraph [0144]

Paragraph [0144] of WO 2014/143941 A1 discloses a claim-like embodiment according to the invention within a series of other claim-like embodiments which extend from paragraphs [0143] to [0210]. Paragraph [0144] reads as follows (emphasis added by the board):

"2. *A stabilized formulation* ***for controlled 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 D_2 and 25-hydroxyvitamin D_3;
and an effective amount of a stabilizing agent, which is optionally a cellulosic compound,
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.*"

1.4.1 The features emphasised by the board in paragraph [0144] constitute two differences from claim 1 of the main request:

- claim 1 is directed to a formulation for sustained release rather than controlled release, and
- claim 1 does not require that the vitamin D compound is for release in the gastrointestinal tract of a subject which ingests the formulation.

For the reasons explained here below, the board holds that paragraph [0144] is not a suitable basis for claim 1, at least due to the second difference.

1.4.2 The appellant provided two arguments as to why omitting the requirement that the formulation must be suitable for the sustained release of the vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation from claim 1 does not add subject-matter. First, the general teaching of WO 2014/143941 A1 was not limited to a formulation which releases the vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation. Therefore, this requirement in paragraph [0144] could be omitted without adding subject-matter. Second, the omitted requirement was implicit in claim 1, meaning that it did not need to be specified.

1.4.3 With regard to the first argument, paragraph [0144] explicitly states that the formulation is (suitable) for controlled release in the gastrointestinal tract of a subject which ingests the formulation. The appellant is right in saying that the general disclosure of WO 2014/143941 A1 does not necessarily require the formulation to be suitable for controlled release in the gastrointestinal tract of a subject which ingests

the formulation. This is indeed the case for the claim-like embodiments described in paragraphs [0143], [0145] and [0147]. However, this cannot mean that the condition explicitly mentioned in paragraph [0144] is not essential for the embodiment disclosed therein. The skilled person would not directly and unambiguously derive from WO 2014/143941 A1 that the specific embodiment in paragraph [0144] can be generalised to formulations that are not suitable for the controlled release of a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation.

1.4.4 With regard to the second argument, the appellant submitted that the requirement that the formulation is suitable for controlled release of a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation can be omitted because it would be implicit in claim 1; the claim requires the formulation to have a storage-stable *in vitro* release profile, which would mean that the claimed formulation is suitable for providing a stable *in vivo* release profile in the gastrointestinal tract of a subject which ingests the formulation.

The respondent rejected this argument because the omitted requirement was introduced as a limitation in dependent claim 5, which reads as follows (emphasis added by the board):

"5. *The formulation of any of the preceding claims, wherein the formulation is an* ***oral formulation*** *for sustained release of the vitamin D compound* ***in the gastrointestinal tract of a subject which ingests the formulation.***".

According to the appellant, the respondent was wrong because claim 5 does not limit the formulation of claim 1 in that it has to be suitable for the sustained release of a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation; this limitation was redundant because it was already implicit in claim 1. The actual limitation introduced in claim 5 was that the formulation is for oral administration. On this point, the appellant stated in its letter of 23 December 2024 (page 4, lines 4 and 5) that "*dependent claim 5 limits the formulation to oral formulations whereas claim 1 is not so limited*".

In the board's view, a formulation suitable for releasing a vitamin D compound in the gastrointestinal tract of a subject which ingests the formulation is necessarily an oral formulation, since ingestion implies oral administration. Consequently, the formulation in paragraph [0144] of WO 2014/143941 A1 must be suitable for oral administration and cannot support claim 1, which is broader because it also encompasses formulations that are not suitable for oral administration. Therefore, paragraph [0144] is not a valid basis for claim 1 of the main request.

Contrary to the board's conclusion on this point, the appellant argued at the oral proceedings before the board that "ingestion" did not necessarily imply oral administration; it merely referred to the act of taking the formulation into the body. Therefore, ingestion would encompass administration routes other than oral administration, e.g. rectal administration. In support of this view, the appellant referred to the claim-like embodiment in paragraph [0168] of WO 2014/143941 A1, which was dependent on the embodiment in paragraph [0144], and defined dosage forms including a

suppository. The appellant also referred to a definition that it had retrieved online during oral proceedings as evidence.

The board does not agree with the appellant's interpretation of the term "ingestion", because it does not reflect the common understanding of the skilled person. Paragraph [0168] of WO 2014/143941 A1 does not support the appellant's interpretation, either. This paragraph discloses "*[a] sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a formulation* ***according to any one of the preceding paragraphs***" (emphasis added by the board). Although one of the dosage forms in paragraph [0168] is clearly not oral, namely the suppository, this does not mean that the formulation in paragraph [0144] can be a suppository; it would be instead a capsule, a tablet, a sachet or a dragee, which are dosage forms compatible with oral administration. The suppositories in paragraph [0168] can be considered for embodiments in which the formulations are not explicitly for controlled release in the gastrointestinal tract of a subject which ingests the formulation, such as the formulations in paragraphs [0143], [0145] and [0147].

1.5 Starting from paragraph [0036]

Paragraph [0036] of WO 2014/143941 A1 discloses (emphasis added by the board):

"*A stabilized formulation according to the disclosure herein, following storage for a period of time, releases an amount of 25-hydroxyvitamin D in* in vitro *dissolution that does not substantially differ from the dissolution of the same formulation just after*

manufacturing and prior to storage. ***For example, in one embodiment,*** *a formulation releases an amount of 25-hydroxyvitamin D during* in vitro *dissolution after exposure to storage conditions of two months at 25 °C and 60% relative humidity that varies at any given dissolution time point after four hours by 30% or less compared to the amount released at the same dissolution time point during* in vitro *dissolution conducted prior to exposing the formulation to the storage conditions (i.e., freshly-produced product).*"

This paragraph teaches that the disclosed stabilised formulations have an *in vitro* release profile that remains stable during storage. As an illustrative example of the stability level of the formulation, paragraph [0036] discloses the stability requirement that has been incorporated into claim 1 of the main request.

Contrary to the appellant's view, the board cannot derive from WO 2014/143941 A1 that the stability level example in paragraph [0036] is generally applicable to all the embodiments disclosed in this patent application, particularly to those set out in claim 1 of the main request which concern formulations characterised *inter alia* by the presence of specific stabilising agents in specific amounts.

1.5.1 The wording in the first sentence of paragraph [0036] "*according to the disclosure herein*" is ambiguous and raises doubts as to whether it refers to the application as a whole or just to preceding paragraph [0035], which refers to formulations "[*d*]*isclosed herein*" and which is the first passage in the detailed description of WO 2014/143941 A1 disclosing the composition of the formulations of the invention. Since

paragraph [0035] is limited to formulations for controlled release in the gastrointestinal tract of a subject which ingests the formulation, it is uncertain whether paragraph [0036] is generally applicable or whether it is limited to formulations for controlled release in the gastrointestinal tract of a subject which ingests the formulation.

In addition, even if paragraph [0036] were considered to be generally applicable, this would not necessarily be the case for the stability-level example disclosed in paragraph [0036] for illustrative purposes ("*[f]or example, in one embodiment*"). This is corroborated by the fact that such a stability requirement is not present in the independent claim-like embodiments in paragraphs [0143], [0145] and [0146].

1.5.2 The appellant also relied on the combination of paragraph [0036] with paragraphs [0009], [0026], [0029], [0030] and [0050] of WO 2014/143941 A1.

Paragraph [0009] does not support the appellant's case in this respect because it explicitly relates to formulations for controlled release in the gastrointestinal tract of a subject which ingests the formulation, a limitation that is missing from claim 1.

Paragraphs [0026] and [0030] teach that sustained release is a particular case of controlled release. They do not contain any information on the composition of the formulation or the place where the vitamin D compound is to be released.

Paragraph [0029] teaches that the vitamin D compound can include 25-hydroxyvitamin D_2, 25-hydroxyvitamin D_3 or a combination of these, although

25-hydroxyvitamin D_3 is the preferred compound and the one tested in the examples.

Paragraph [0050] discloses multiple embodiments of the nature and amount of the stabilising agents, including those recited in claim 1 of the main request.

Even assuming that, as alleged by the appellant, the teaching of paragraph [0036] were applicable to all the embodiments of the invention, the board has already explained in point 1.5.1 above that this is not the case for the stability-level example disclosed in this paragraph for illustrative purposes. WO 2014/143941 A1 does not directly and unambiguously disclose the combination of the example in paragraph [0036] with each of the embodiments selected from paragraphs [0029] and [0050] required to arrive at the combination of features in claim 1.

1.5.3 Therefore, paragraph [0036] of WO 2014/143941 A1 does not support the particular combination of features defined in claim 1, either.

1.6 As a consequence, the board concludes that claim 1 of the main request contains subject-matter which extends beyond the content of the earliest application as filed, contrary to Article 76(1) EPC.

2. Auxiliary request 1 - added subject-matter (Article 76(1) EPC)

Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the list of substances comprised in the stabilising agent has been limited to a cellulosic compound, i.e. poloxamers, poly(ethylene

oxide) polymers, povidones, fumed silicas and combinations thereof have been deleted from the list.

At the oral proceedings before the board, the appellant did not make any additional submissions with regard to auxiliary request 1. In the statement of grounds of appeal (point 14.1.7 on pages 132 and 133), the primary basis for claim 1 of auxiliary request 1 cited by the appellant was paragraph [0144] of WO 2014/143941 A1. Considering that claim 1 of auxiliary request 1 is missing the limitation that the vitamin D compound must be suitable for controlled release in the gastrointestinal tract of a subject which ingests the formulation, paragraph [0144] is not a valid basis for the reasons put forward in relation to claim 1 of the main request.

Therefore, claim 1 of auxiliary request 1 also adds subject-matter (Article 76(1) EPC).

3. *Auxiliary request 2 - added subject-matter (Article 76(1) EPC)*

Claim 1 of auxiliary request 2 is directed to "*[a] sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a stabilised formulation*", wherein the stabilised formulation is as defined in claim 1 of auxiliary request 1. Therefore, as also remarked by the respondent in its reply to the statement of grounds of appeal (point 2 on pages 40 and 41), claim 1 of auxiliary request 2 is still missing the requirement that the formulation is for controlled release in the gastrointestinal tract of a subject which ingests the formulation.

The primary basis for claim 1 of auxiliary request 2 in WO 2014/143941 A1 cited by the appellant was paragraph [0144] in combination with paragraph [0168]. The latter paragraph refers to "*[a] sustained release dosage form in the form of a capsule, tablet, sachet, dragee, or suppository comprising a formulation according to any one of the preceding paragraphs*".

At the oral proceedings before the board, the appellant submitted that the sustained-release forms recited in claim 1 of auxiliary request 2 were implicitly suitable for controlled release in the gastrointestinal tract of a subject which ingests the formulation.

The board does not agree. It is technically untenable that a suppository according to claim 1 of auxiliary request 2 is necessarily based on a formulation that is suitable for controlled release in the gastrointestinal tract of a subject which ingests (i.e. swallows) the formulation. The appellant's contention is not supported by WO 2014/143941 A1 either, since the dosage forms in paragraph [0168] are not necessarily based on paragraph [0144]. They can be based on formulations that are not required to be suitable for controlled release in the gastrointestinal tract of a subject which ingests the formulation, such as those in paragraphs [0143], [0145] and [0147].

Therefore, the combination of paragraph [0144] with paragraph [0168] does not support claim 1 of auxiliary request 2, which consequently adds subject-matter (Article 76(1) EPC).

4. Auxiliary request 3 – extension of patent protection (Article 123(3) EPC)

4.1 In the decision under appeal, the opposition division considered that auxiliary request 3 (then auxiliary request 22) did not add subject-matter (page 40, penultimate paragraph). The respondent has not contested this conclusion in these appeal proceedings. The only objection raised in the decision against present auxiliary request 3 was that it extended the protection conferred by the patent as granted (decision, pages 41 to 49).

4.2 Like claim 12 as granted, claim 1 of auxiliary request 3 is directed to a sustained-release dosage form in the form of a capsule, tablet, sachet, dragee or suppository. The opposition division considered that two aspects of claim 1 of auxiliary request 3 extended patent protection beyond the limits conferred by claim 12 as granted:

First, claim 1 of auxiliary request 3 was directed to a sustained-release dosage form which comprises a formulation for **controlled** release, while claim 12 as granted defines a sustained-release dosage form which comprises a formulation for **sustained** release.

Second, the limitation in claim 1 as granted that the stabilising agent was present in the formulation in an amount of at least 5 wt.% has been removed from claim 1 of auxiliary request 3. As a consequence, the stabilising agents recited in claim 1 as granted could be present in amounts below 5 wt.%.

The respondent has not made any submissions regarding the second aspect in these appeal proceedings.

4.3 With regard to the first aspect, claim 1 of auxiliary request 3 defines a sustained-release dosage form which comprises a stabilised formulation for controlled release. The parties agreed that sustained release is a particular type of controlled release and that the latter fully encompasses the former.

4.3.1 The opposition division and the respondent were of the view that it could not be ruled out that there are sustained-release dosage forms according to claim 1 of auxiliary request 3 containing a formulation that provides a type of controlled release of the vitamin D compound that is not sustained. Nevertheless, as noted by the appellant, neither the opposition division nor the respondent could identify a dosage form according to claim 1 of auxiliary request 3 that was not encompassed by claim 12 as granted.

4.3.2 The board agrees with the appellant that the hypothetical case considered by the opposition division and the respondent is not realistic in technical terms. More importantly, however, the board agrees with the appellant that the limitations in the formulation of claim 1 of auxiliary request 3 render the formulation implicitly suitable for sustained release of the vitamin D compound.

In addition to the vitamin D compound, the formulation in claim 1 contains a very specific combination of excipients which amount to at least 90 wt.% of the formulation, namely 30 to 35 wt.% mineral oil, 20 wt.% paraffin, 20 to 25 wt.% glycerol monostearate, 10 wt.% of a mixture of lauroyl macrogolglycerides and lauroyl

polyoxyglycerides, and 10 to 15 wt.% hydroxy propyl methylcellulose (HPMC). A person skilled in the field of pharmaceutical formulations would understand that a formulation containing these excipients does not release the vitamin D compound immediately. This view is reinforced by the requirement for the formulation to exhibit an *in vitro* release profile which extends over at least four hours; a requirement that is fulfilled by the formulation tested in the examples of the patent, which is a formulation in accordance with the narrow composition defined in claim 1 of auxiliary request 3 (see paragraph [0098] and Figures 1 to 3).

Therefore, the controlled release mentioned in claim 1 of auxiliary request 3 is intrinsically sustained release and does not extend the protection conferred by the patent as granted.

4.4 With regard to the second aspect, it is undisputed that HPMC is a stabilising agent in accordance with claim 1 as granted and that it belongs to the group of cellulose compounds (see also claim 9 as granted). HPMC is present in the composition in claim 1 of auxiliary request 3 in an amount of 10 to 15 wt.%. Therefore, the formulation in claim 1 of auxiliary request 3 contains at least 5 wt.% of stabilising agent, as required by claim 1 as granted, and does not extend patent protection.

The opposition division seems to have interpreted claim 1 as granted as if it required that each of the materials recited in the claim from which the stabilising agent can be selected had to be present in an amount of at least 5 wt.% (decision, page 47, fourth paragraph). However, such an interpretation cannot be derived from the wording of claim 1 as granted, in

which the "at least 5 wt.%" feature clearly refers to the stabilising agent as a whole and not to each of the materials from which the stabilising agent can be selected.

4.5 In conclusion, claim 1 of auxiliary request 3 meets the requirements of Article 123(3) EPC.

5. Auxiliary request 3 - remittal

Auxiliary request 3 was first filed as auxiliary request 22 at the oral proceedings before the opposition division. The only objection discussed for this request was extension of patent protection; the respondent declared that it did not have any added subject-matter objection (minutes of oral proceedings, page 3).

On 9 February 2023, the opposition division had issued a preliminary opinion based on claim 1 as granted and claim 1 of four auxiliary requests which contained the amount of the stabilising agent as the only additional limitation. Claim 1 of auxiliary request 3 is considerably more limited than claim 1 of the requests on which the opposition division's opinion was based because it contains important limitations in relation to the components and their amounts in the formulation. By way of these limitations, the claimed formulation is closely aligned with the formulation tested in examples in the patent. Therefore, it is doubtful that the opposition division's preliminary opinion remains relevant to auxiliary request 3. For instance, the preliminary opinion dealt with sufficiency objections, numerous novelty objections and inventive-step objections starting from 13 different documents as the closest prior art. In contrast, the respondent has

raised no sufficiency or novelty objections against auxiliary request 3, and the inventive-step objections are based on only two documents as the closest prior art.

Furthermore, the parties have not provided in these appeal proceedings inventive-step arguments specifically dealing with the limitations now in auxiliary request 3. The respondent merely stated that "*claim 1 of AR3 lacks inventive step over both closest prior art documents D3 and D17 for similar reasons provided above for claim 1 of the MR*" (reply to the appeal, page 41, last sentence). The appellant has not provided specific inventive-step arguments for auxiliary request 3, either.

Consequently, given that the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner (Article 12(2) RPBA), the board considered that there were special reasons within the meaning of Article 11 RPBA to remit the case to the opposition division for further prosecution based on auxiliary request 3.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division for further prosecution.

The Registrar: The Chairman:

A. Vottner A. Usuelli

Decision electronically authenticated