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Datasheet for the decision of 12 April 2024

Case Number: R 0008/19

Appeal Number: T 1537/16 - 3.3.07

Application Number: 10700730.4

Publication Number: 2379063

IPC: A61K9/28, A61K31/215, A61K31/225, A61P17/06, A61K9/20, A61P1/04, A61P1/16, A61P3/10, A61P5/14, A61P5/16, A61P7/06, A61P13/12, A61P17/00, A61P19/02, A61P21/00, A61P25/02, A61P25/04, A61P27/02, A61P37/02, A61P37/06

Language of the proceedings: EN

Title of invention:

PHARMACEUTICAL FORMULATION COMPRISING ONE OR MORE FUMARIC ACID ESTERS IN AN EROSION MATRIX

Patent Proprietor:

FWP IP APS

Opponents:

Generics [UK] Limited
Biogen MA Inc.
Wohldorff GmbH

Headword:

Relevant legal provisions:
EPC Art. 56, 112a(2)(c), 113(1)

Keyword:
Petition for review - unallowable

Decisions cited:
R 0001/08, R 0004/08, R 0012/09, R 0015/10, R 0015/12, R 0001/13, R 0008/13, R 0016/13, R 0004/14, R 0003/15, R 0005/16, R 0010/17, R 0005/22

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Case Number: R 0008/19

D E C I S I O N
of the Enlarged Board of Appeal
of 12 April 2024

Petitioner: (Opponent 1)	Generics [UK] Limited (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1AG (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Other party: (Opponent 3)	Wohldorff GmbH Neuer Wall 72 20354 Hamburg (DE)
Representative:	Simandi, Claus Simandi Patentanwälte Kurfürstendamm 45 10719 Berlin (DE)
Other party: (Patent Proprietor)	FWP IP APS Østergade 24 A 1100 København K (DK)
Representative:	HGF HGF Limited 1 City Walk Leeds LS11 9DX (GB)
Decision under review:	**Decision of the Technical Board of Appeal 3.3.07 of the European Patent Office of 18 April 2019**

Composition of the Board:

Chair	C. Josefsson
Members:	F. Blumer
	P. Scriven
	D. Rogers
	I. Beckedorf

Summary of Facts and Submissions

Overview

I. The petition for review concerns the decision T 1537/16 of Technical Board of Appeal 3.3.07 ("the Board"), which was pronounced in oral proceedings of 18 April 2019, its written reasons being dispatched on 15 July 2019. The petition for review was filed by opponent 1 ("O1"). It concerns the Opposition Division's decision to reject the oppositions against the European patent 2 379 063. The Board set aside the decision under appeal and concluded that the patent could be maintained on the basis of the proprietor's auxiliary request 1 (in the Board's order, it is referred to as the "first auxiliary request").

II. The petitioner claims that a fundamental violation of its right to be heard occurred since it transpired from the written decision that the Board, in acknowledging inventive step for the subject-matter claimed by auxiliary request 1, formulated the objective technical problem in a manner that was never put forward by any party or by the Board itself.

The patent

III. The patent relates to a pharmaceutical formulation comprising one or more fumaric acid esters in an erosion matrix. The formulation can be used, in particular, for the treatment of psoriasis. Independent claim 1 of the patent read as follows:

"A pharmaceutical formulation in the form of an erosion matrix tablet comprising:

i) 10 % to 80 % by weight of one or more fumaric acid esters selected from di-(C_1-C_5)alkylesters of fumaric acid and mono-(C_1-C_5)alkylesters of fumaric acid, or a pharmaceutically acceptable salt thereof, as an active substance;

ii) 1-50 % by weight of one or more rate-controlling agents; and

an enteric coating, wherein said enteric coating is applied at a level of 1.5 - 3.5 % by weight of the core,

wherein erosion of said erosion matrix permits controlled or sustained release of said active substance."

The Opposition Division's decision

IV. Three oppositions to the patent were filed. All the opponents relied *inter alia* on the ground of opposition under Article 100(a) EPC in connection with Article 56 EPC (lack of inventive step). The Opposition Division ("OD") decided that none of the grounds of opposition prejudiced maintenance of the patent.

V. With respect to inventive step, the OD considered example 16 of document D1 (WO 2006/037342) to be the closest prior art, and found that the claimed invention differed in that D1 neither disclosed an erosion matrix tablet nor an enteric coating applied at a level of 1.5 - 3.5 % of the core by weight. It then assessed the technical effect of these distinguishing technical features.

VI. The proprietor had argued that the differences led to improvements in view of several technical effects (fewer side effects; a simplified production process; more rapid release of the fumaric ester in the

intestine, without release in the stomach; and reduction in variability of the pharmacokinetic parameters). However, the OD considered that these effects were not sufficiently proven, in particular because the experimental data disclosed in the patent or later submitted by the proprietor did not show a comparison with the closest prior art. It reformulated the technical problem as the provision of an alternative (point 7.4 of the Reasons), recognising that the tablets according to the patent "show the zero-order release profile, as expected for tablets with a drug release driven by erosion (figure 1 of the patent at issue)" (point 7.5).

VII. Nevertheless, the OD took the view that neither distinguishing feature was suggested in D1 or any other cited document dealing with a fumaric ester as the active ingredient. The skilled person would not have regarded an erosion matrix as his or her first choice but would have needed to make a purposeful selection. An erosion matrix tablet would rather have been pursued in exceptional cases, in which a zero-order release profile (as shown in figure 1 of the patent) had shown itself to be advantageous for administering a particular active ingredient. Furthermore, the skilled person would not have expected that an enteric coating, applied at the specified level defined, would have met the requirements posed on an enteric coating. The release profile shown in figure 1 of the patent (no drug release under simulated gastric conditions) amounted to a surprising technical effect (point 7.6 of the Reasons).

The appeal proceedings

VIII. Notices and grounds of appeal were filed by all three opponents. Their arguments differed to some extent, including with respect to the objection of lack of inventive step.

IX. While all opponents followed the OD as to the closest prior art (example 16 of D1), O1 started from the assumption ("we will assume", see point (11) of its grounds of appeal and point (11) of its letter of 27 June 2018) that the OD was correct in identifying the two distinguishing features, i.e. the use of an erosion matrix and the proportion of enteric coating. The objective technical problem was the mere provision of an alternative composition, not of an improved composition. The distinguishing features lacked synergy, and each of them was obvious. O1 took issue with the OD's view that an erosion matrix would rather have been pursued by the skilled person in exceptional cases, in which a zero-order release profile had shown itself to be advantageous. In O1's view, zero-order release resulted in constant plasma concentrations of a drug and was consequently generally desirable for extended release formulations. Erosion matrix tablets were a standard type of formulation, and the expectation of obtaining zero-order kinetics (the use of the term "first-order kinetics" in points (49) and (56) of opponent 1's grounds of appeal appears to be an obvious mistake) provided specific motivation for selecting this type of tablet.

X. Opponent 2 ("O2") contested the OD's novelty analysis and disputed that the two identified features actually distinguished the invention. In particular, it argued that the tablet of example 16 of D1 was also an erosion

matrix tablet, which permitted the controlled or sustained release of the active substance. If the claimed subject-matter were for some reason considered novel over this example, there was no technical difference that could support an inventive step. In any case, there was no evidence that the claimed pharmaceutical formulation provided any improvement compared to example 16 of D1. In line with the contested decision and contrary to the proprietor's point of view, the problem had to be formulated as the provision of an alternative pharmaceutical formulation. However, the OD was wrong to conclude that the claimed solution would not have been obvious.

XI. In its grounds of appeal, opponent 3 ("O3") agreed with the proprietor that an erosion matrix should have zero-order kinetics. However, example 16 of D1 also provided an erosion matrix. O3 submitted comparative test results in order to show that zero-order kinetics would be achieved with this example, independently of the proportion of enteric coating. The claimed proportion of enteric coating was arbitrary and amounted to a "Scheinmerkmal" (phantom feature).

XII. In response to the appeals, the proprietor emphasised that the claimed erosion matrix tablets permitted a controlled or sustained release of the active substance, by means of a specific mechanism which was reflected in a specific release profile, namely a linear or zero order release (see reply to the appeals of 28 February 2017, p. 2; see also p. 10: "release control by erosion will lead to a zero order release profile, and this was generally known."). It defended the OD's novelty analysis, *inter alia* by submitting that the tablets of example 16 of D1 were not erosion matrix tablets, since their release profile was clearly

non-linear. With regard to inventive step, the proprietor insisted that, based on the combination of the distinguishing features, the claimed formulation had the major advantage of reduced variability in pharmacokinetic parameters. Contrary to the OD's view, which did not take this effect into account, the technical problem solved by the invention was not merely the provision of an alternative, but the provision of an improved pharmaceutical formulation having a reduced variability in pharmacokinetic parameters. The conclusion reached by the OD, that the requirements of Article 56 EPC were met, had all the more to apply, if the advantages achieved were properly taken into account.

XIII. The proprietor, furthermore, made clear that the auxiliary requests presented before the Opposition Division were also maintained in appeal proceedings. Claim 1 of auxiliary request 1 was restricted, in comparison to claim 1 of the patent, in that "the rate-controlling agent is a water-soluble polymer."

XIV. Thereafter, O2 withdrew its opposition and, consequently, lost its status as party to the proceedings. O3 withdrew its appeal. While remaining a party as of right, O3 took no further part in the appeal and the review proceedings.

XV. In further submissions by O1 (dated 10 October 2017 and 27 June 2018) and by the proprietor (dated 14 February 2018, the parties essentially reiterated their positions. O1 contested the effects on which the proprietor relied, in particular the alleged reduction in pharmacokinetic variability. The auxiliary requests did not change the issues and the objective technical problem with respect to them was still the provision of

an alternative tablet. O1 expressed the view that the primary difference between the parties lay in the formulation of the objective technical problem. The proprietor submitted that, with respect to auxiliary request 1, the objective technical problem was also the provision of an improved pharmaceutical formulation, namely a formulation having improved pharmacokinetic parameters.

XVI. In a communication under Article 15(1) RPBA (2007), the Board *inter alia* expressed the provisional opinion that the closest prior art, for assessing inventive step, was D1. It considered that
- the only distinguishing feature between the subject-matter of claim 1 of the patent and example 16 of D1 was the amount of enteric coating;
- there was no support for the existence of the technical effect alleged by the proprietor (reduced pharmacokinetic variability);
- the technical problem was the provision of an alternative; and
- the claimed solution appeared to be obvious.
With respect to auxiliary request 1, the Board noted that example 16 of D1 remained relevant and that alternative water-soluble polymers were also disclosed in the description of D1 and some of its other examples.

XVII. In a reply dated 28 March 2019, the proprietor challenged the Board's preliminary opinion. The petitioner did not respond to the Board's preliminary opinion.

XVIII. In the oral proceedings before the Board, the first point of discussion was whether the subject-matter of claim 1 of the main request or claim 1 of auxiliary

requests 1, 2, or 3 involved an inventive step in particular considering documents D1 and D10. After deliberation, the Chair announced that the Board had come to the conclusion that claim 1 of the main request did not involve an inventive step, whereas claim 1 of auxiliary request 1 did. After discussion of further objections to claim 1 of the latter request, the Board announced its decision that the patent could be maintained as amended according to auxiliary request 1.

Review proceedings

XIX. O1 filed a petition for review on 25 September 2019, alleging that its right to be heard had been fundamentally violated. It had only learnt from the written reasons of the decision that, when acknowledging inventive step with respect to auxiliary request 1, the Board had redefined the objective technical problem; and they had done this in a completely unexpected manner. At no point in the proceedings had the Board indicated that it was minded to define the problem in a manner that was never put forward by any party nor by the Board itself.

XX. The definition of the objective technical problem was not a minor issue, but was fundamental to the assessment of inventive step. Parties to proceedings at the EPO were expected to use the problem-solution approach and clearly define the objective technical problem. If the Board intended to define a different problem, it also had to define that problem clearly for the parties. Unless an opponent knew how the problem was being defined, it was impossible to present arguments on inventive step. If the petitioner had been informed about the possibility of defining the problem in the manner the Board relied on, it would have needed

to present totally different arguments and to discuss, in particular, whether the problem had been solved, whether it had been solved across the full scope of the claim and, even if it had been solved, whether it had been solved in an obvious manner.

XXI. It was completely unacceptable to discover that the Board had departed completely from the arguments advanced by either part on such an important issue, only in the written decision. In the light of the Enlarged Board of Appeal's decisions R 16/13, R 3/15 and R 10/17, this deficiency amounted to a fundamental violation of the petitioner's right to be heard (the petitioner refers to "R 13/15" rather than to R 3/15, but this appears to be a typographical mistake).

XXII. The petitioner requested that
- the decision under review be set aside; and
- proceedings be re-opened.

Further, it conditionally requested oral proceedings under Article 116 EPC.

XXIII. By order of 22 July 2020, the case was referred to a five-member composition of the Enlarged Board, under Rule 109(2)(b) EPC.

XXIV. The proprietor and O3 were notified of the referral to the five-member composition of the Enlarged Board. While O3 did not react, the proprietor filed comments on 1 October 2020. It requested that the petition for review "be rejected in its entirety as inadmissible and/or unallowable". As an auxiliary measure, it requested oral proceedings.

XXV. The proprietor primarily argued that the petitioner's request rested exclusively on a single point, namely

"the allegation that the objective technical problem defined by the Board of Appeal for the first auxiliary request does not correspond to the problem as defined by any party, or the Board of Appeal, at any stage of the proceedings." Numerous passages were quoted from the proceedings before he Opposition Division and the Board, in which reference was made to the release profiles of the claimed pharmaceutical formulations or to the rate-controlling agents they comprised.

XXVI. In a letter filed on 5 November 2020, the petitioner filed a response to the proprietor's submission of 1 October 2020. It mainly argued that the problem eventually used in the Board's decision differed from the problems discussed during the appeal proceedings.

XXVII. In response, the proprietor reiterated, in its letter of 14 January 2021, that the petitioner had had ample opportunity to present its case during appeal proceedings. Referring to various decisions of the Enlarged Board, the proprietor argued that the petitioner's right to be heard had not been fundamentally violated, even if the objective technical problem identified in the written decision had not been spelled out to the petitioner in advance.

XXVIII. The Enlarged Board summoned the parties to oral proceedings and issued a communication under Article 13 of the Rules of Procedure of the Enlarged Board of Appeal, on 20 November 2023.

XXIX. The petitioner made further submissions in a letter of 22 January 2024.

XXX. Oral proceedings before the Enlarged Board were held on 12 April 2024, in the presence of the petitioner. The

other parties (O3 and the proprietor) were not represented at the oral proceedings.

XXXI. At the oral proceedings, the Chair summarised the parties' final requests as follows:

- The petitioner requested
  - that the decision under review be set aside and
  - that proceedings before the Board be re-opened.
- The proprietor requested that the petition for review be rejected as inadmissible or unallowable.
- O3 had not filed any requests in review proceedings.

XXXII. The decision was announced at the end of the oral proceedings before the Enlarged Board.

Reasons for the Decision

Admissibility of the petition

1. The petition for review complies with all requirements for admissibility, including the exception to the precondition of an objection under Rule 106 EPC.

Allowability of the petition

Legal background

2. Decisions of a board of appeal may only be based on grounds or evidence on which the parties have had an opportunity to present their comments (Article 113(1) EPC). This means that a party must not be taken by surprise by the reasons for the decision referring to unknown grounds or evidence.

3. "Grounds or evidence" under Article 113(1) EPC is to be understood as the essential legal and factual reasoning on which the decision is based (see, for example, R 5/22, Reasons 9). The right to be heard is observed if a party had the opportunity to comment on the decisive considerations and the relevant passages of the prior art on which a decision is based (see, for example, R 16/13, Reasons 3.3 and 5.2). The right to be heard is violated if a board of appeal supports its decision on grounds or evidence not presented during the proceedings, without giving the parties an opportunity to comment on them (see R 16/13, Catchword). All parties must have an opportunity to comment on the decisive aspects of the case.

4. On the other hand, the board must be able to draw its own conclusion from the discussion of the grounds put forward (see R 8/13, Reasons 2; R 16/13, Reasons 3.3). Thus, the right to be heard does not go so far as to impose an obligation on a board to disclose to the parties, in advance, how and why, on the basis of the decisive issues under discussion – or at least those foreseeable as the core of the discussion – it will come to its conclusion. This is part of the reasoning given in the written decision (R 1/08, Reasons 3.1; R 15/12 Reasons 5; R 16/13, Reasons 3).

5. In the present case, a cornerstone of the Board's inventive step reasoning with respect to claim 1 of auxiliary request 1 was the construction of the objective problem solved by the claimed subject-matter. In line with its reasoning concerning the main request, the Board did not follow the proprietor's view that the objective problem consisted of the provision of an improved pharmaceutical formulation with reduced

variability in its pharmacokinetic parameters, since it considered that a corresponding effect had not been demonstrated. But it also did not follow the petitioner's view that the problem was merely the provision of an alternative tablet. Instead, it considered that the objective problem solved was the provision of a pharmaceutical formulation with a zero order release profile.

6. The question arises, whether the Board's reliance on an objective problem that was never mentioned to the petitioner amounts to a fundamental violation of the right to be heard. In the Enlarged Board's view, this question cannot generally be answered in the affirmative. The application of the problem-solution approach can be viewed as a method of determining and reasoning whether a claimed invention fulfils the requirement of inventive step (Articles 52 and 56 EPC).

7. There is no obligation to apply the problem-solution approach. However, regardless of whether and how the problem-solution approach is used, the right to be heard means, at least, that the parties must be heard on the basis of the reasoning used in the decision. In the context of the problem-solution approach, there should normally have been a discussion on the relevant prior art, the differences between the prior art and the claimed invention, and the technical relevance of these differences. Within the framework of what has been addressed in the course of these discussions, the deciding organ should be free to apply the problem-solution approach as it sees fit, and even identify an objective problem that has not been explicitly spelled out as such during the proceedings. In any case, the objective problem eventually used in the reasoning has to be based on technical effects (or the lack of any)

and the features of the invention causally linked to such effects, upon which the parties had an opportunity to comment.

8. In its letter of 22 January 2024 and during oral proceedings before the Enlarged Board, the petitioner basically agreed with this legal analysis. On the one hand, the petitioner accepted that, within the framework of what has been discussed with the parties, the deciding organ should be free to apply the problem-solution approach as it saw fit, and this could include the identification of an objective problem that had not been explicitly spelled out. On the other hand, the petitioner argued that the parties should be able to foresee the factual basis on which the deciding organ could base its problem-solution approach, and must not be surprised by the reasoning in the decision.

9. In this context, the Enlarged Board notes that, according to consistent case law, subjective surprise has no bearing on whether a party knew the issues and had an adequate opportunity to comment upon (see, for example, R 12/09 of 15 January 2010, Reasons 13; R 15/10, Reasons 11; R 5/16, Reasons 19). In addition, reasoning based on the submissions of another party cannot be surprising (R 4/08, Reasons 3.3). For the purposes of Article 113(1) EPC, it is sufficient if a reason corresponds to an argument forwarded by another party (R 1/13, Reasons 10). Whether a party can be considered to have been taken by surprise is assessed on an objective basis (R 4/14, Reasons 3).

Technical context

10. Claim 1 of the patent as granted (main request in appeal) reads (to simplify, one passage has been abbreviated):

"A pharmaceutical formulation in the form of an erosion matrix tablet comprising:

i) 10 % to 80 % by weight of [...] as an active substance;

ii) 1-50 % by weight of one or more rate-controlling agents; and

an enteric coating, wherein said enteric coating is applied at a level of 1.5 - 3.5 % by weight of the core,

wherein erosion of said erosion matrix permits controlled or sustained release of said active substance."

11. In claim 1 of auxiliary request 1, the rate-controlling agent (component ii) of the matrix) is specified as follows (emphasis added to highlight the difference to the main request):

ii) 1-50 % by weight of one or more rate-controlling agents, wherein the rate-controlling agent is a water-soluble polymer;

12. The active substance defined in feature i) is not a critical issue in the present proceedings. The active substance of the claimed pharmaceutical formulation, a coated tablet, is released in a controlled or sustained manner, in the gastric environment of the patient. The "enteric coating" is resistant to gastric acid and prevents dissolution or disintegration in the patient's stomach. In the body region where the active substance is released, the "rate-controlling agent", in which the active substance is embedded, provides for the claimed "controlled or sustained release" of the active substance.

13. The "matrix" formed by the active substance (i) and the rate-controlling agent (ii) is referred to as "erosion matrix", and "erosion" permits the controlled or sustained release of the active substance, according to claim 1.

14. The relevant technical issues of the claimed subject-matter, in view of the prior art, can be summarised as follows:
    (a) the claimed amount of the enteric coating, which is smaller than in the prior art;
    (b) the variability of the pharmacokinetic parameters of the individual tablets (expressed as the coefficient of variation, i.e. the ratio of the standard deviation to the mean, see paragraph [0045] of the patent); and
    (c) the dissolution release profile or kinetic model, i.e. the amount of released active substance over time (see paragraphs [0162] to [0166] of the patent). Three kinetic models are described in said passage, the first referred to as "zero order". In the course of the proceedings, zero order was understood to refer to the release of active substance at a constant rate.

15. Paragraphs [0162] to [0166] form the only passage in the patent specification that refers to kinetic models. Neither "zero order" nor any of the other kinetic model is referred to otherwise; and they are not brought into connection with any technical feature of the claimed tablets or the prior art.

Discussion of the relevant grounds and evidence in appeal

16. The written reasons show that, with respect to the main request, the Board essentially endorsed the view it had already expressed in its communication. In particular it considered that
- D1 disclosed an erosion matrix permitting controlled release;
- the erosion matrix of claim 1 was not limited to any specific kind of release profile, in particular not a zero order profile;
- the only distinguishing feature over D1 was the amount of enteric coating;
- the technical problem was merely the provision of an alternative composition, since the improvement alleged by the proprietor, i.e. the reduced variability in pharmacokinetic parameters had not been credibly demonstrated;
- the choice of the specific amount of coating was an arbitrary choice and, as a routine modification, obvious for the skilled person.

17. With respect to auxiliary request 1, the Board's decision on inventive step, which gave rise to the petition, can be summarized as follows:
- D1 (example 16) remained the closest prior art;
- the objective technical problem was not the one proposed by the proprietor, i.e not the provision of an improved pharmaceutical formulation with a reduced variability in its pharmacokinetic parameters;
- the technical problem was rather the provision of a pharmaceutical formulation showing zero order release, and it was solved by the claimed subject-matter by means of the combination of water-soluble rate-controlling polymers and the thin enteric coating (point 5.4 of the Reasons, two last paragraphs);

- the solution would not have been obvious.

18. For the reasons given below, the Enlarged Board comes to the conclusion that the Board based its decision only on grounds that were objectively foreseeable by the parties, in view of their submissions and the Board's statements during the appeal proceedings.

19. During the entire proceedings leading to the decision under review, the zero order release profile - the provision of which was eventually adopted by the Board as the objective technical problem - was discussed, either as a quality of the erosion matrix or as a feature that was desirable *per se*. In its grounds of appeal, the petitioner stated in paragraph (50): "Moreover, zero-order release results in constant plasma concentrations of a drug and is consequently generally desirable for extended release formulation."

20. In the decision under review, zero order release was discussed in the context of the question as to whether and in what respect the subject-matter of claim 1 of the main request could be distinguished over example 16 of document D1. The Board did not follow the proprietor's position that D1 did not relate to erosion matrices and that the erosion matrix required by claim 1 necessarily provided a zero order release profile. The Board concluded that "the erosion matrix and supposedly linked release profile cannot constitute a further difference between the claimed subject-matter and the disclosure of D1" (point 1.2.2 of the Reasons).

21. In this context, the Board relied on Figure 1 of the patent, acknowledging that it showed the release of tablets having a zero order release profile. The Board, however, pointed out that the figure referred to

specific examples of the patent, all of them comprising hydroxy propylcellulose, a water-soluble polymer, as rate-controlling agent. The functional feature "rate-controlling polymer" remained a general term, in the view of the Board, which did not reflect the specific type of (water-soluble) polymer used in the examples of Figure 1 (point 1.2.2 of the Reasons).

22. From this reasoning concerning the main request, it may already be concluded that there was a connection between the sort of polymer and the release profile.

23. In the course of review proceedings, the proprietor argued that, from reading section 1.2.2 of the decision, it was evident that the technical effect of zero order release was presented with the sole purpose of having it acknowledged as a distinguishing feature, and, therefore, it was obvious to put forward that effect for incorporation into the objective technical problem (letter of 1 October 2020, point 5.1). The petitioner replied to this argument as follows: "The patentee's position is essentially that the arguments they made in relation to the distinguishing feature for the main request disclosed the problem as defined by the TBA for the first auxiliary request" (letter of 5 November 2020, point (11)).

24. One has to conclude, from the file, that the discussion on the main request covered the zero order release profile in connection with the disputed distinguishing feature, the erosion matrix. Not only the problem eventually used in the context of auxiliary request 1 (to achieve a zero order release profile) but also the solution (the use of a water-soluble polymer) was explicitly discussed in the context of the main request. According to the minutes of oral proceedings

before the Board, inventive step was discussed for both the main request and auxiliary request 1, before oral proceedings were interrupted for the Board's deliberation. The parties did not know the Board's conclusion on the main request, when auxiliary request 1 was discussed.

25. In situations in which requests are increasingly restricted in a converging manner (e.g. in view of specific examples or embodiments), the parties should be aware that certain effects of the claimed invention may be acknowledged by the deciding organ only for a higher-ranking request.

26. It must be concluded that the facts and evidence underlying the Board's decision on auxiliary request 1 were discussed in a way that gave the petitioner sufficient opportunities to be heard. As shown in the Board's reasons concerning the main request, the distinguishing feature "erosion matrix" and the relation of this feature with the release profile was discussed (see also points 22 ff above), although with the conclusion that "the erosion matrix and supposedly linked release profile cannot constitute a further difference between the claimed subject-matter and the disclosure of D1" (point 1.2.2 of the Reasons). However, the Board's reasons concerning the main request indicate how the additional distinguishing feature could be established, namely, by the use of a water-soluble polymer as a rate-controlling agent. In particular, it was noted that the examples depicted in Figure 1 of the patent, which showed a zero order release profile, comprised a water-soluble polymer (top of page 13 of the decision).

27. These considerations by the Board were based on discussions during written appeal proceedings. In its letter of 28 March 2019, the proprietor explained, in the context of auxiliary request 1, that examples 18 and 22 (as shown in Figure 1 of the patent), for which clinical data were provided, both employed water soluble polymers for rate control. Under these circumstances, it could not be surprising that the Board connected the additional limiting feature of claim 1 of auxiliary request 1 ("wherein the rate-controlling agent is a water-soluble polymer") with the generally acknowledged advantages of a zero-release profile, which profile was also set out for examples 18 and 22 in Figure 1 of the patent.

Conclusion

28. The Enlarged Board concludes that no fundamental violation of Article 113 EPC occurred, since the parties had the opportunity to comment upon the grounds and evidence on which the decision under review is based, in particular, on the additional limiting feature of auxiliary request 1 and the technical effect eventually used by the Board in its application of the problem-solution approach.

Order

For these reasons it is decided that:

The petition for review is rejected as unallowable.

The Registrar: The Chair:

N. Michaleczek C. Josefsson

Decision electronically authenticated