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**Datasheet for the decision of 1 July 2021**

**Case Number:** T 2106/18 - 3.3.07

**Application Number:** 12193798.1

**Publication Number:** 2564839

**IPC:** A61K9/28, A61K31/215, A61P17/06, A61K9/20, A61K31/225

**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

**Opponent:**
Generics (U.K.) Limited

**Headword:**
Pharmaceutical formulation comprising a fumaric acid ester in an erosion matrix/ FWP IP APS

**Relevant legal provisions:**
RPBA 2020 Art. 13(2), 11
EPC Art. 56
EPC R. 106

**Keyword:**
Reformulation of the technical problem
Remittal to the opposition division (No)
Main request - Inventive step (Yes)
Objection under Rule 106 EPC (Dismissed)

**Decisions cited:**
T 1537/16

Europäisches Patentamt
European Patent Office
Office européen des brevets

**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
Fax +49 (0)89 2399-4465

**Case Number: T 2106/18 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 1 July 2021

| | |
|---|---|
| **Appellant:** (Opponent) | Generics (U.K.) Limited<br>Station Close<br>Potters Bar<br>Hertfordshire EN6 1TL (GB) |
| **Representative:** | Elkington and Fife LLP<br>Prospect House<br>8 Pembroke Road<br>Sevenoaks, Kent TN13 1XR (GB) |
| **Respondent:** (Patent Proprietor) | FWP IP APS<br>Østergade 24 A<br>1100 København K (DK) |
| **Representative:** | HGF<br>1 City Walk<br>Leeds LS11 9DX (GB) |
| **Decision under appeal:** | **Decision of the Opposition Division of the European Patent Office posted on 2 July 2018 rejecting the opposition filed against European patent No. 2564839 pursuant to Article 101(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | A. Usuelli |
| **Members:** | D. Boulois |
| | P. Schmitz |

## Summary of Facts and Submissions

I. European patent No. 2 564 839 was filed as a divisional application of the patent EP 2 379 063 upon which the decision T 1537/16 is based. It was granted on the basis of a set of 11 claims.

Independent claim 1 as granted read as follows:

"1. A pharmaceutical formulation in the form of an erosion matrix tablet comprising:
i) 35 - 55 % by weight of dimethyl fumarate;
ii) 3 - 6 % by weight of hydroxypropyl cellulose; and
iii) 40 - 60 % by weight of lactose."

II. An opposition was filed under Article 100 (a), (b) and (c) EPC on the grounds that its subject-matter lacked inventive step, was not sufficiently disclosed and extended beyond the content of the (earlier) application as filed.

III. The appeal lies from the decision of the opposition division to reject the opposition.

IV. The documents cited during the opposition proceedings included the following:
D1: WO 2006/037342
D5: US 6 509 376
D6: US 6 355 676
D9: Tabendeh et al., Iranian J. of Pharm. Res., p. 201-206
D10: WO 2007/042034

D15: Handbook of Pharmaceutical Excipients, 4th Edition, page 289
D19: US 2004/002544
D20: Pharmaceutics, The Science of Dosage Form Design
D26: "Comparative trials on disintegration behavior of DMF tablets", ConsuPharm GmbH
D27: Attachment A: Comparative Tests with Fumaderm® as reference product
D28: Reply to the Int. Search Opinion filed in response to the communication pursuant Rule 161 EPC
D39: Declaration of Prof. Dr. A Fahr
D40: Eudragit RS 30D, product information sheet (Evonik)
D41: Second Declaration of C. Galetzka
D43: Pharmaceutics, The Science of Dosage Form Design, p. 288-305, 2006

V. According to the decision under appeal, claims 1-11 as granted met the requirements of Article 76(1) EPC, and the claimed invention was sufficiently disclosed.

As regards inventive step, D10 was considered to represent the closest prior art in view of its examples 1 and 5. The distinguishing features were the erosion release mechanism, and the amounts of HPC and lactose. The problem was defined as the provision of an alternative controlled or sustained release formulation of DMF. The claimed solution was inventive.

VI. The opponent (hereinafter the appellant) filed an appeal against said decision.

VII. With its reply to the statement of grounds of appeal dated 11 January 2019, the patent proprietor (hereinafter the respondent), filed auxiliary requests

6-8, and confirmed auxiliary requests 1-5 as filed in the opposition proceedings.

VIII. In a communication pursuant to Article 15(1) RPBA dated 4 February 2021, the Board stated *inter alia* that, with regard to inventive step, it tended to agree with the opposition division that the informative value of the technical data provided did not provide reliable evidence of a technical effect related to an improvement regarding pharmacokinetic properties. Moreover, the Board referred to the respondent's arguments that the claimed composition provided a zero order release and that there appeared to exist a technical effect linked with the claimed solution which was also acknowledged in decision T 1537/16 relating to the parent patent of the present contested patent. The preliminary opinion of the Board was that the claimed subject-matter appeared to be inventive.

IX. With a letter dated 21 May 2021, the respondent argued on inventive step, and submitted in particular that the claimed solution was associated with the technical effect of providing zero-order release profiles and this had to be taken in account when assessing inventive step.

X. Oral proceedings took place on 1 July 2021 by videoconference.

XI. Requests

The appellant requested that the decision under appeal be set aside and the patent be revoked. It additionally requested that the respondent's submission to include the "zero-order release profile" into the objective technical problem when assessing inventive step not be

admitted. If this reformulated technical problem was admitted, remittal to the opposition division was requested. It further requested not to admit any of the auxiliary requests of the respondent.

The respondent requested that the appeal be dismissed, alternatively that the decision under appeal be set aside and the patent be maintained according to one of the sets of claims filed as auxiliary requests 1-5 with letter of 5 April 2018 before the opposition division, or auxiliary requests 6-8 filed with letter of 11 January 2019.

XII. The arguments of the appellant may be summarised as follows:

Request not to admit the "zero-order release profile" into the objective technical problem when assessing inventive step

The respondent did not mention in its reply to the statement of grounds of appeal that the technical problem to be solved related to a zero order release. It was the Board which mentioned this point in their communication for the first time and the respondent only in reply thereto took up this point. The incorporation of said zero order release in the technical problem was therefore an amendment to its case. In the present case, the Board used the available data to provide something new. The Board had a duty to be impartial and to treat all parties fairly and accordingly should not have done this.

The respondent could not be expected to respond to the definition of the problem as defined by the Board, and

it should therefore not be admitted into the proceedings.

If this request was not allowed, the case should be remitted to the opposition division for a re-examination.

Main request - Inventive step

D10 was the closest prior art, in view of its examples 1 and 5. There were three distinguishing features, namely the release from an erosion matrix tablet rather than a multiple unit tablet, the presence of 3-6 wt% HPC, and the presence of 40-60 wt% lactose.

Claim 1 did not require the HPC to cause sustained release, and there was no limitation in the claim that explicitly or implicitly required a low proportion of another sustained release polymer to be present. The claim defined only 78 wt% of the composition (35 wt% DMF, 3 wt% HPC, and 40 wt% lactose) and so the other 22 wt% of the composition could indeed comprise further sustained release polymers. Moreover, the function of the claimed excipients was not given in claim 1.

The comparisons given in example 43 of the patent and in D29 were irrelevant for the reasons given in the opposition division's decision, and it was not credible that an improvement in pharmacokinetic variance existed over the whole scope of the claims. The reduced pharmacokinetic variance was irrelevant and the data on file did not make it plausible that the problem of reducing PK variance was solved.

Since the zero-order release was not a feature of the claim, it should not be considered. Moreover, there was

no evidence that this effect was linked with a distinguishing feature and that it was achieved over the whole scope of the claims.

The problem was seen as the provision of an alternative sustained release composition.

With regard to the obviousness of the solution, the erosion matrix was a standard type of formulation which was known from the common general knowledge (see D39 and D21). In the absence of any unexpected advantage or prejudice, the skilled person was free to apply the common general knowledge to the prior art and thereby prepare further types of sustained release formulation. Therefore, the use of an erosion matrix formulation was obvious.

With regard to the zero-order release, the claim did not include any explicit limitation to the release profile of the composition. Moreover, the obtention of a zero order release did not present any difficulty. Any erosion matrix formulation, which according to the patentee released active ingredient by gradual erosion of layers of the matrix, fell within the scope of the claim. The skilled person would have prepared such a formulation with the hope that it provided zero-order release. Therefore, in the absence of a prejudice or an unexpected technical effect, this choice of formulation type represented one obvious choice and the patent lacked an inventive step.

With regard to the claimed amount of HPC, the claim included no limitation that required the composition to extend release over a particular time period, and the patentee had provided no evidence showing that the claimed proportion of HPC extended release as

effectively as a higher proportion; the type of HPC was also not limited to a specific HPC. Further, the skilled person was aware that an "ideal" matrix formulation should included as little sustained release polymer as possible. D15 disclosed that the amounts of HPC to be used as a binder was 2-5 wt%.

With regard the claimed amount of lactose, this feature merely defined a broad, standard proportion of a common diluent, as shown in D42.

The claimed subject-matter was therefore obvious.

XIII. The arguments of the respondent may be summarised as follows:

Request not to admit the "zero-order release profile" into the objective technical problem when assessing inventive step

The discussion on the zero-order release and its incorporation in the problem to be solved was not an amendment to the case. It was a technical feature which has been discussed during the opposition proceedings and presented again by the appellant and the respondent in the appeal proceedings. This point was a key feature and a key difference with the closest prior art, on which the appellant had commented within the context of obviousness. The arguments remained the same, and had been there from the outset.

The Board had a right to review the parties' cases, and to come to a decision on inventive step.

The appellant had an opportunity to respond to the Board's communication but had refrained to do so before the oral proceedings.

Main request - Inventive step

D10 was the closest prior art, in particular its example 5. The distinguishing features were the erosion matrix, and the nature and amounts of excipients.

The fact that the tablets of Example 1 in D10 contained PEG 400 and/or lactose did not make them erosion matrix tablets. These excipients were not present to provide sustained release. The definition of the term "erosion matrix" was well defined in the patent and in D25. The tablet of D10 was a tablet dosage form that depended upon intrinsic diffusion processes which could not be regarded as an erosion matrix tablet. Moreover, a disintegrating tablet dosage form could also not be regarded as an erosion matrix tablet. The tablets of D10 were multiple-unit diffusion tablets that relied on tablet disintegration into granules and subsequent intrinsic diffusion-controlled drug release from small discrete DMF-containing units. This was different from the claimed formulation which was a single-unit, monolithic erosion matrix.

The comparative data of the patent and of D27 had to be taken in account.

The difference in the obtained type of release profile demonstrated a technical effect, namely the zero order release kinetics that were provided by the claimed formulations. For an erosion mediated release mechanism, there was a linear relationship between cumulative drug amount and time span. Figures 1 and 5

of D10 showed the in vitro dissolution profile of tablets according to Examples 1 and 5 of D10 respectively and these profiles were clearly non-linear and not of zero order release. D26 was also supportive of this technical distinction and effect. The study in D26 showed that the tablets according to the invention were different from the multi-particulate tablets of D10 and were non-disintegrating matrix systems.

The skilled person would have known that the design of a controlled release product providing zero-order type release was difficult to achieve (see D43).

The use of low amounts of HPC was not obvious as rate controlling polymer, as shown by D15, in particular not in the context of an erosion matrix providing a zero order release.

The use of a high lactose level was also not obvious for the obtention of an erosion matrix with a high drug load that needed to maintain structural integrity for a prolonged period, in view of the water-solubility of lactose.

In conclusion, the claimed solution was associated with the technical effect of providing zero-order release profiles and this had to be taken into account when assessing inventive step. As demonstrated above, it would not have been obvious to the skilled person to arrive at formulations providing a zero-order release mechanism in order to solve the objective technical problem.

## Reasons for the Decision

1. Appellant's request not to admit the inclusion of any reference to the zero-order release profile into the definition of the objective technical problem.

1.1 At the beginning of the oral proceedings, the appellant requested that the respondent not be admitted to include any reference to the zero-order release profile into the definition of the objective technical problem when assessing inventive step. It took the view that this was an amendment to the respondent's case which should not be admitted under Article 13(2) RPBA 2020.

1.2 Article 13(2) RPBA 2020 stipulates that any amendment to a party's appeal case after notification of a summons to oral proceedings shall, in principle, not be taken into account, unless there are exceptional circumstances which have been justified by cogent reasons. Thus, a condition for not admitting a party's submission under Article 13(2) RPBA 2020 is that this constitutes an amendment to its case. This is however, not the situation here.

1.3 In the written appeal proceedings, i.e in the statement of grounds of appeal and the response thereto, the technical problem for assessing inventive step was defined by the parties as follows:
- according to the appellant, the problem to be solved was the provision of an alternative sustained release form (point 45 of the statement setting out the grounds of appeal),
- according to the respondent, the problem to be solved was the provision of an improved pharmaceutical formulation, namely a formulation having improved pharmacokinetic properties, particularly a reduced

variability of pharmacokinetic parameters (AUC and $C_{max}$) (point 3.2.4 of the reply).

The Board noted in its preliminary opinion that it agreed with the opposition division that the technical data on file did not provide reliable evidence of a technical effect relating to an improvement of some pharmacokinetic properties, particularly a reduced variability of pharmacokinetic parameters (AUC and $C_{max}$) (point 10.5.3). The Board further stated that one of the respondent's main arguments was that the claimed composition provided a zero-order release (point 10.5.4). In this regard the Board made reference to the paragraph "No pointer to zero order type release being required" on page 11 of the reply of 11 January 2019, this paragraph being part of the discussion on the obviousness of the composition of claim 1 starting on page 9 and following the definition of the technical problem. The Board, in agreement with the respondent, confirmed that there appeared to exist a technical effect linked with the claimed solution, said effect being the zero-order release. These considerations were made by the Board in the context of discussing the technical problem (paragraphs 10.4 to 10.5.4 of the communication before the section “Obviousness of the Solution”). The existence of this technical effect was also acknowledged by the opposition division in its decision (see page 19) where it stated that a zero-order release is shown in Figure 1 of the patent. This statement was made after the definition of the technical problem made in paragraph 4.4 of the decision in the context of the assessment of the obviousness of the solution (paragraphs 4.6 to 4.6.3).

In its statement of grounds of appeal, the appellant also considered whether the formulation of claim 1

provided a zero-order release. This was made in the context of the discussion on the obviousness of the solution, as it was made by the opposition division (points 55 to 62).

It follows, that the discussion on the zero-order release effect was part of the appeal procedure since its start and was also part of the discussion made before the opposition division. Thus, the effect of the zero-order release had been a point of discussion throughout the whole procedure.

1.4 When assessing inventive step, the Boards apply the so-called problem solution approach which essentially consists of the following steps (see Case Law of the Boards of Appeal I.D.2):

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(a) identifying the "closest prior art",
(b) assessing the technical results (or effects) achieved by the claimed invention when compared with the "closest state of the art" established,
(c) defining the technical problem to be solved as the object of the invention to achieve these results, and
(d) examining whether or not a skilled person, having regard to the state of the art within the meaning of Article 54(2) EPC, would have suggested the claimed technical features in order to obtain the results achieved by the claimed invention .

The opposition division and the parties incorporated the assessment of the zero-order release effect in the step of examining the obviousness of the solution (step (d) above). In its communication of 4 February 2021, the Board applied the problem and solution approach and considered it more appropriate to discuss this effect

in the context of the discussion concerning the technical problem.

This does not in essence modify the approach followed by the opposition division in its decision and by the respondent. Indeed, in its letter of reply the respondent essentially argued that the compositions of the patent achieve a zero-order release profile and that the relevant prior art documents do not suggest the provision of compositions providing this type of release (page 11). Although the technical problem formulated in the reply does not contain any reference to the zero-order release, the reasoning on page 11 is essentially equivalent to argue that the problem of providing a formulation resulting in a zero-order release has been solved in a non-obvious manner. Thus, shifting the discussion concerning the release profile from the "obviousness" part of the problem solution approach to the part relating to the definition of the technical problem does not go beyond the framework established by the arguments contained in the letter of reply and therefore does not involve any fundamental change of the respondent's argumentation.

It follows from the above considerations that the respondent's appeal case is not amended for the sole reason that the technical problem includes a reference to the achievement of a zero-order release.

Thus the Board has no discretion not to admit these submissions into the proceedings since they do not constitute an amendment to the party's case and consequently admits them.

1.5 The Board is furthermore of the view, that even if the position of the appellant were to be followed in

considering the inclusion of a reference to the zero-order release as an amendment to the party's case, then such an amendment would be admissible under Article 13(2) RPBA as an appropriate reaction from the side of the respondent to the approach followed by the Board in its communication.

2. Remittal to the opposition division

Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

As explained above, including a reference to the zero-order release in the formulation of the technical problem does not result in any substantial change to the discussion on inventive step. Moreover, this inclusion was already envisaged in the communication issued by the Board on the 4 February 2020. Thus, the appellant had more than four months time to prepare its case.

Thus, in the exercise of its discretion, the Board decides not to allow the request of the appellant to remit the case to the opposition division.

3. Main request - Inventive step

3.1 The invention relates to an erodible matrix comprising DMF and a rate-controlling agent (see par. [0001] of the specification).

Claim 1 as granted reads:
"1. A pharmaceutical formulation in the form of an erosion matrix tablet comprising:

i) 35-55% by weight of dimethyl fumarate;
ii) 3-6% by weight of hydroxypropyl cellulose;
iii) 40-60% by weight of lactose".

3.2 Examples 1 and 5 of document D10 were considered as suitable starting points by all parties, and by the opposition division in its decision. Example 16 of D1 is identical to example 1 of D10.

3.2.1 Example 1 of D10 discloses the preparation of a granulate of 50 g DMF, 12 g Ethylcellulose and 3 g Polyethylenglycole 400. A placebo granulate is prepared comprising Tablettose® (lactose) and Avicel® (cellulose) in equal shares and granulated with 2% povidone. 60 parts of the DMF- granulate and 38 parts of the placebo-granulate are mixed, one part magnesium stearate and one part Aerosil is added and the blend is compressed to tablets.

The amounts by weight of the main components in the final tablet of example 1 are therefore the following:
(i) DMF 46.2%
(ii) Ethylcellulose 11.1%
(iii) PEG 400 2.8%
(iv) Lactose 18.6%
(v) Cellulose 18.6%

3.2.2 Example 5 of D10 discloses the preparation of a granulate comprising 50 g DMF mixed with 50 g Eudragit RS® D30. A placebo granulate is prepared comprising Tablettose® and Avicel® in a ratio of 1:2 and granulated with 2% povidone. 60 parts of the DMF granulate, 37 parts of the placebo-granulate and one part carboxymethylcellulose are mixed, one part magnesium stearate and one part of silicon dioxide are

added, and the blend is compressed to tablets; the final tablet comprises less than 35 weight% of DMF.

The amounts by weight of the main components in the final tablet of example 5 are therefore the following:
(i) DMF 30%
(ii) Eudragit RS30D 30%
(iii) Lactose 12.1%
(iv) Cellulose 24.2%

3.2.3 The distinguishing features between the claimed subject-matter and the disclosure of examples 1 and 5 of D10 are at least the presence of "ii) 3-6% by weight of hydroxypropyl cellulose and iii) 40-60% by weight of lactose".

3.2.4 While both parties considered that the erosion matrix was a further distinguishing feature, the Board has some doubts that this is indeed the case for the reasons provided in paragraph 10.3.3 of the communication of 4 February 2021. However, in view of the conclusion on inventive step on the basis of the distinguishing features defined in 3.2.3 above (see below), this issue does not need to be decided.

3.3 According to the appellant, the technical problem to be solved is the provision of an alternative sustained release form.

According to the respondent, the problem is the provision of an improved pharmaceutical formulation, namely a formulation having improved pharmacokinetic properties, particularly a reduced variability of pharmacokinetic parameters (AUC and Cmax). In addition, the respondent states that the claimed solution is associated with a zero-order release.

3.4 The appellant considered that the problems of improving the pharmacokinetic properties, i.e. the reduction of the pharmacokinetic variance, and the provision of a zero order release, were not solved.

The respondent referred to Example 43 of the contested patent and to the experimental tests of D27 to demonstrate the existence of an effect on the pharmacokinetic properties. Figure 1 of the patent was presented as an evidence of the zero order release.

3.4.1 Example 43 of the contested patent provides a comparison between formulations of the claimed invention and the commercial product Fumaderm®, whose composition is given in paragraph [0004] of the contested patent; in view of this disclosure, said commercial product Fumaderm® appears to include a coating, and does not comprise lactose, which is the case for the formulations of examples 1 and 5 of D10. Example 43 does therefore not provide a direct comparison with the formulations of example 1 and 5 of D10.

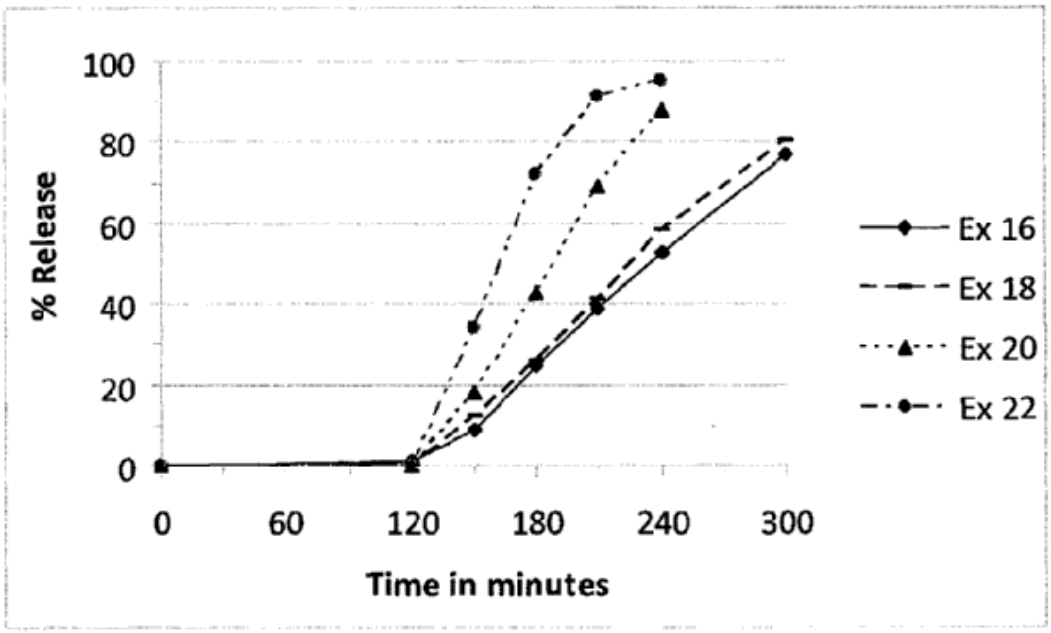
D27 relates to a comparison between the commercial product Fumaderm® and two formulations 1 and 2, whose composition appear to correspond to the composition of the tablet of example 5 of D10. Said experiments D27 are provided to give an indirect comparison combined with the experiments of Example 43 of the contested patent, to demonstrate the existence of an effect on the pharmacokinetic properties.

Thus, neither Example 43 of the patent, nor D27, show an effect over the specific formulation of example 1 of D10. As convincingly argued by the appellant, even

assuming that an effect is shown for formulations 1 and 2 of D27, corresponding to example 5 of D10, it is not credible that the same effect can be achieved relative to example 1 of D10, in particular in view of the difference in formulations between both examples. It appears indeed not possible to extrapolate the result for example 5 to an example relating to a composition including a different extended release polymer.

Consequently, it is not possible to conclude to the existence of a technical effect concerning the pharmacokinetic properties over at least the specific formulation of example 1 of D10.

3.4.2 Figure 1 of the patent (see below) shows the in vitro release profile of the formulations of Examples 16, 18, 20 and 22 of the patent:



It can be seen that the release profile of the compositions was of a zero-order, after a delay due to the enteric coating.

On the other hand, the dissolution profile of example 1 of D10 is shown in Figure 1 of the same document (see below), and shows a release profile of an uncoated tablet which is clearly different from a zero-order release. This difference was also acknowledged by the appellant.

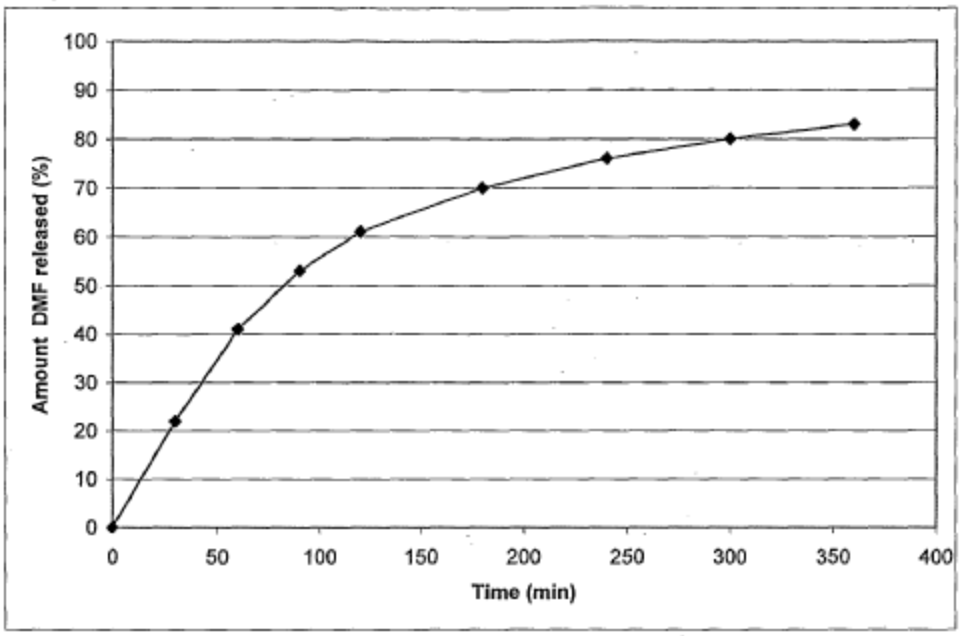



Fig. 1

D10 gives also in its further Figure 5 the in vitro release profile for the formulation of Examples 5 which confirms the same kind of release as the formulation of

example 1 of D10.

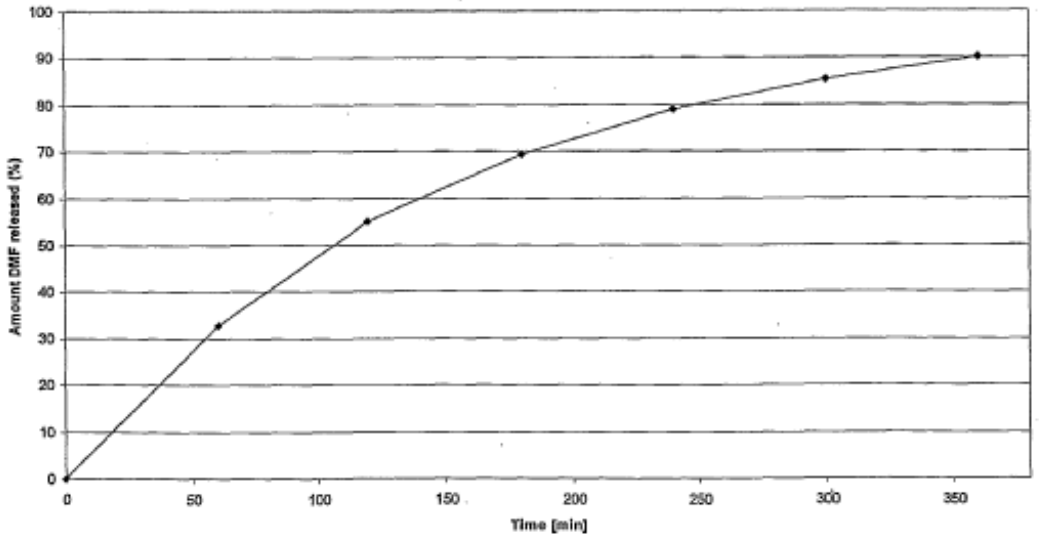



Fig. 5

A direct comparison between both types of in vitro release profiles shows a clear difference between the in vitro release profile obtained with a formulation as claimed, which is a zero-order release, from the release profile obtained with a tablet according to the formulations of in particular examples 1 and 5 of D10, which is not of the zero-order type.

Hence, it is clear that the distinct nature and amount of the excipients, namely the presence of 3-6% by weight of hydroxypropyl cellulose and 40-60% by weight of lactose shows an effect on the release of DMF.

The existence of this effect, invalidates the definition of the problem as posed by the appellant, i.e the provision of an alternative formulation. When it is established that there exists a technical effect over the closest prior art, this effect has indeed to be taken into account in the formulation of the technical problem.

Accordingly, the technical problem is the provision of a pharmaceutical formulation showing a zero-order release.

3.5 The question remaining to be answered is whether the skilled person, starting from the disclosure of D10, would arrive at the subject-matter of claim 1 of the main request in an obvious manner in order to solve the problem posed.

There is no teaching in D10 on how to obtain a tablet showing a zero-order release, and there is also no teaching to prepare tablets comprising HPC and lactose, even less in the claimed concentration range, i.e. 3-6% by weight of hydroxypropyl cellulose and 40-60% by weight of lactose. It is in particular not possible to see in the disclosure of examples 1 and 5 of D10 any suggestion or incentive to incorporate HPC in said formulations and to simultaneously increase the amounts of lactose, even less in order to get a different release profile of DMF.

The appellant cited also D15 and D19 to show that it was obvious to prepare compositions comprising proportions of HPC commonly used as a binder (see D15), or as a coating (see D15 or example 1 of D19) and that the claim did not include a surprising amount of HPC, and covered compositions comprising a standard amount of HPC for a standard purpose. None of said cited documents relate however to tablets comprising a high load of DMF, or to tablets providing a zero order release, and none of them discloses a combination of lactose and HPC with the claimed amounts. Documents D15 and D19 therefore cannot render the claimed solution obvious.

Furthermore, the Board sees no reason to doubt that HPC is used as rate controlling polymer in the claimed formulation. The use of 3-6 wt% of HPC in the context of an erosion matrix is not disclosed or suggested in any cited document, and is not obvious for at least this reason. Moreover, as argued by the respondent, D15 teaches that HPC should be used in amounts of 15-35 wt% as extended release matrix former (see D15, Table 1), and there is no teaching in the prior art that would motivate the skilled person to depart from the teaching of D15, and employ the lower amount of 3-6 wt% of HPC in the context of an erosion matrix tablet containing a high drug load of DMF, let alone any teaching that would give the skilled person a reasonable expectation of success that doing so would provide a zero order release.

As to lactose, it is true that it is a common excipient for the preparation of tablets. The use of such a high lactose level in combination with a high drug loading and HPC in the claimed erosion matrix tablet for the obtention of a zero-order release is however not disclosed or suggested in any cited document. Such use is also not obvious in view of the water solubility properties of lactose and the necessity to maintain the structural integrity of the tablet.

It is also not possible to conclude, as the appellant did, that any erosion matrix will provide a zero-order release; it is indeed clear that the choice of the excipients and their amounts for obtaining an erosion matrix and possibly a zero order release is not obvious. D43 confirms that the design of a controlled release product providing a zero order release is

difficult to achieve (see D43, page 293, left hand column).

The solution according to the subject-matter of claim 1 is therefore not obvious and the main request meets the requirements of Article 56 EPC.

4. Objection under Rule 106 EPC

4.1 At the end of the oral proceedings before the Board, the appellant raised an objection in respect of a procedural defect under Rule 106 EPC.

The objection read as follows:
"The Board of Appeal contravened the opponent’s right to be heard by allowing the patentee to amend their case to introduce a new definition of the objective technical problem that had been raised for the first time by the Board of Appeal in their preliminary opinion, and about which the opponent was therefore not provided with an adequate opportunity to make comments."

4.2 The Board cannot acknowledge a violation of the appellant's right to be heard.

As mentioned above under point 1.3, a possible reformulation of the objective technical problem for assessing inventive step was envisaged in the Board's preliminary opinion. This formulation concerned a topic, i.e. the "zero-order release", which was already present and discussed in the opposition proceedings and in the decision of the opposition division, as well as in the statement of grounds of appeal and the reply thereto. Thus, the introduction of a reference to the zero-order release effect in the formulation of the

technical problem does not result in any substantial change of the framework of the discussion on inventive step. Furthermore considering that the preliminary opinion pursuant to Article 15(1) RPBA was issued nearly five months before the date of the oral proceedings, the Board fails to see how this reformulation of the technical problem could compromise the possibility for the appellant to adequately prepare its case on inventive step.

The appellant had an opportunity to respond to the Board's communication in writing, an opportunity the appellant decided to not take.

During the oral proceedings, the appellant presented its comments on both lines of argument which had been presented by the respondent, i.e. that the technical problem to be solved was the provision of an improved pharmaceutical formulation and, additionally, that the technical problem was the provision of a composition comprising dimethylfumarate showing a zero-order release profile. It considered that both problems were not solved by the patent in suit and that accordingly the technical problem could only be seen in the provision of an alternative. Consequently, the appellant had an adequate opportunity to present its comments on the definition of the objective technical problem during oral proceedings. This was acknowledged by the appellant itself in the course of the oral proceedings as reported in the minutes.

4.3 Consequently, the appellant's objection in respect of a procedural defect under Rule 106 EPC is dismissed.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated